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(54) **FISTULA TREATMENT DEVICES AND RELATED METHODS**

(75) Inventors: **Harold F. Carrison**, Pleasanton, CA (US); **Yolanda Pacho Huynh**, San Jose, CA (US)

(73) Assignee: **CURASEAL INC.**, Santa Clara, CA (US)

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,324,520 A 7/1943 Lamson
2,510,766 A 6/1950 Surface
2,564,399 A 8/1951 Franken
(Continued)

FOREIGN PATENT DOCUMENTS

DE 2637119 A1 3/1977
EP 1985247 A1 10/2008
(Continued)

OTHER PUBLICATIONS

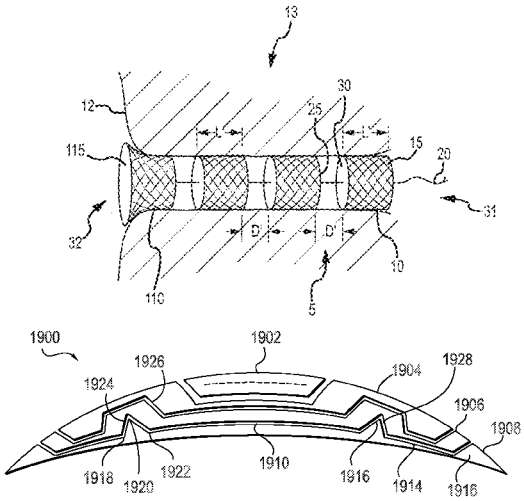
International Search Report, in connection with International Patent application No. PCT/US2012/042805, Nov. 28, 2012, (pp. 1-5).
(Continued)

*Primary Examiner* — Katherine M Shi
(74) *Attorney, Agent, or Firm* — Dorsey & Whitney LLP

(57) **ABSTRACT**

Disclosed herein are implantable fistula treatment devices and related methods. The fistula closure device comprises a distal anchor and a proximal anchor attached by a connecting member, such as a suture. Individual porous bodies are threaded directly or indirectly over the connecting member. The distal anchor comprises a plurality of foldable members threaded onto the connecting member. The foldable members are arranged in increasing surface area from distal to proximal, and each is further configured to form a mechanical interfit with adjacent foldable members to reduce sliding between members when they are tensioned together.

**21 Claims, 54 Drawing Sheets**



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(56) **References Cited**

U.S. PATENT DOCUMENTS


| | | | | |
|---|---|---|---|---|
| 2,934,068 | A | | 4/1960 | Graham, Jr. et al. |
| 3,447,533 | A | | 6/1969 | Spicer |
| 3,882,858 | A | | 5/1975 | Klemm |
| 4,057,535 | A | | 11/1977 | Lipatova et al. |
| 4,241,735 | A | | 12/1980 | Chernov |
| 4,365,621 | A | | 12/1982 | Brundin |
| 4,390,018 | A | | 6/1983 | Zukowski |
| 4,532,926 | A | | 8/1985 | O'Holla |
| 4,669,473 | A | | 6/1987 | Richards et al. |
| 4,705,040 | A | | 11/1987 | Mueller et al. |
| 4,744,364 | A | | 5/1988 | Kensey |
| 4,795,438 | A | | 1/1989 | Kensey et al. |
| 4,836,204 | A | | 6/1989 | Landymore et al. |
| 4,852,568 | A | | 8/1989 | Kensey |
| 4,890,612 | A | | 1/1990 | Kensey |
| 4,917,089 | A | | 4/1990 | Sideris |
| 4,935,028 | A | | 6/1990 | Drews |
| 4,983,177 | A | | 1/1991 | Wolf |
| 5,021,059 | A | | 6/1991 | Kensey et al. |
| 5,053,046 | A | | 10/1991 | Janese |
| 5,061,274 | A | | 10/1991 | Kensey |
| 5,108,421 | A | | 4/1992 | Fowler |
| 5,122,136 | A | | 6/1992 | Guglielmi et al. |
| 5,192,301 | A | | 3/1993 | Kamiya et al. |
| 5,192,302 | A | | 3/1993 | Kensey et al. |
| 5,222,974 | A | | 6/1993 | Kensey et al. |
| 5,242,456 | A | | 9/1993 | Nash et al. |
| 5,258,042 | A | | 11/1993 | Mehta |
| 5,282,827 | A | | 2/1994 | Kensey et al. |
| 5,306,254 | A | | 4/1994 | Nash et al. |
| 5,312,435 | A | | 5/1994 | Nash et al. |
| 5,334,217 | A | | 8/1994 | Das |
| 5,350,399 | A | * | 9/1994 | Erlebacher et al. ..... 606/213 |
| 5,354,295 | A | | 10/1994 | Guglielmi et al. |
| 5,370,660 | A | | 12/1994 | Weinstein et al. |
| 5,374,261 | A | | 12/1994 | Yoon et al. |
| RE34,866 | E | | 2/1995 | Kensey et al. |
| 5,391,183 | A | | 2/1995 | Janzen et al. |
| 5,411,520 | A | | 5/1995 | Nash et al. |
| 5,433,727 | A | | 7/1995 | Sideris |
| 5,441,517 | A | | 8/1995 | Kensey et al. |
| 5,522,836 | A | | 6/1996 | Palermo |
| 5,531,757 | A | | 7/1996 | Kensey et al. |
| 5,531,759 | A | | 7/1996 | Kensey et al. |
| 5,540,680 | A | | 7/1996 | Guglielmi et al. |
| 5,545,178 | A | | 8/1996 | Kensey et al. |
| 5,549,633 | A | | 8/1996 | Evans et al. |
| 5,582,619 | A | | 12/1996 | Ken |
| 5,591,204 | A | | 1/1997 | Janzen et al. |
| 5,593,422 | A | | 1/1997 | Muijs Van de Moer et al. |
| 5,609,628 | A | | 3/1997 | Keranen |
| 5,620,461 | A | | 4/1997 | Muijs Van De Moer et al. |
| 5,624,449 | A | | 4/1997 | Pham et al. |
| 5,643,254 | A | | 7/1997 | Scheldrup et al. |
| 5,645,558 | A | | 7/1997 | Horton |
| 5,649,949 | A | | 7/1997 | Wallace et al. |
| 5,662,681 | A | | 9/1997 | Nash et al. |
| 5,669,905 | A | | 9/1997 | Scheldrup et al. |
| 5,676,689 | A | | 10/1997 | Kensey et al. |
| 5,681,334 | A | | 10/1997 | Evans et al. |
| 5,700,277 | A | | 12/1997 | Nash et al. |
| 5,707,393 | A | | 1/1998 | Kensey et al. |
| 5,713,891 | A | | 2/1998 | Poppas |
| 5,725,552 | A | | 3/1998 | Kotula et al. |
| 5,743,905 | A | | 4/1998 | Eder et al. |
| 5,749,891 | A | | 5/1998 | Ken et al. |
| 5,752,974 | A | | 5/1998 | Rhee et al. |
| 5,766,219 | A | | 6/1998 | Horton |
| 5,782,860 | A | | 7/1998 | Epstein et al. |
| 5,785,679 | A | | 7/1998 | Abolfathi et al. |
| 5,810,884 | A | | 9/1998 | Kim |
| 5,824,054 | A | | 10/1998 | Khosravi et al. |
| 5,833,705 | A | | 11/1998 | Ken et al. |
| 5,853,418 | A | | 12/1998 | Ken et al. |
| 5,855,578 | A | | 1/1999 | Guglielmi et al. |
| 5,861,004 | A | | 1/1999 | Kensey et al. |
| 5,879,366 | A | | 3/1999 | Shaw et al. |
| 5,904,703 | A | | 5/1999 | Gilson |
| 5,911,731 | A | | 6/1999 | Pham et al. |
| 5,916,236 | A | | 6/1999 | Muijs Van de Moer et al. |
| 5,925,037 | A | | 7/1999 | Guglielmi et al. |
| 5,928,226 | A | | 7/1999 | Guglielmi et al. |
| 5,935,145 | A | | 8/1999 | Villar et al. |
| 5,935,147 | A | | 8/1999 | Kensey et al. |
| 5,944,714 | A | | 8/1999 | Guglielmi et al. |
| 5,947,962 | A | | 9/1999 | Guglielmi et al. |
| 5,957,900 | A | | 9/1999 | Ouchi |
| 5,957,948 | A | | 9/1999 | Mariant |
| 5,976,126 | A | | 11/1999 | Guglielmi |
| 5,989,281 | A | | 11/1999 | Barbut et al. |
| 5,990,379 | A | | 11/1999 | Gregory |
| 6,004,338 | A | | 12/1999 | Ken et al. |
| 6,007,563 | A | | 12/1999 | Nash et al. |
| 6,010,498 | A | | 1/2000 | Guglielmi |
| 6,010,517 | A | | 1/2000 | Baccaro |
| 6,013,084 | A | | 1/2000 | Ken et al. |
| 6,033,423 | A | | 3/2000 | Ken et al. |
| 6,045,569 | A | | 4/2000 | Kensey et al. |
| 6,045,570 | A | | 4/2000 | Epstein et al. |
| 6,056,768 | A | | 5/2000 | Cates et al. |
| 6,063,100 | A | | 5/2000 | Diaz et al. |
| 6,066,133 | A | | 5/2000 | Guglielmi et al. |
| 6,077,260 | A | | 6/2000 | Wheelock et al. |
| 6,080,183 | A | | 6/2000 | Tsugita et al. |
| 6,083,220 | A | | 7/2000 | Guglielmi et al. |
| 6,087,552 | A | | 7/2000 | Gregory |
| 6,090,125 | A | | 7/2000 | Horton |
| 6,090,130 | A | | 7/2000 | Nash et al. |
| 6,171,326 | B1 | | 1/2001 | Ferrera et al. |
| 6,179,857 | B1 | | 1/2001 | Diaz et al. |
| 6,179,863 | B1 | | 1/2001 | Kensey et al. |
| 6,183,491 | B1 | | 2/2001 | Lulo |
| 6,187,027 | B1 | | 2/2001 | Mariant et al. |
| 6,190,400 | B1 | | 2/2001 | Van De Moer et al. |
| 6,203,563 | B1 | | 3/2001 | Fernandez |
| 6,231,562 | B1 | | 5/2001 | Khosravi et al. |
| 6,238,403 | B1 | | 5/2001 | Greene et al. |
| 6,270,495 | B1 | | 8/2001 | Palermo |
| 6,287,318 | B1 | | 9/2001 | Villar et al. |
| 6,296,658 | B1 | | 10/2001 | Gershony et al. |
| 6,306,153 | B1 | | 10/2001 | Kurz et al. |
| 6,315,787 | B1 | | 11/2001 | Tsugita et al. |
| 6,371,972 | B1 | | 4/2002 | Wallace et al. |
| 6,383,204 | B1 | | 5/2002 | Ferrera |
| 6,409,721 | B1 | | 6/2002 | Wheelock et al. |
| 6,454,780 | B1 | | 9/2002 | Wallace |
| 6,476,069 | B2 | | 11/2002 | Krall et al. |
| 6,503,527 | B1 | | 1/2003 | Whitmore et al. |
| 6,538,026 | B1 | | 3/2003 | Krall et al. |
| 6,551,303 | B1 | | 4/2003 | Van Tassel et al. |
| 6,551,305 | B2 | | 4/2003 | Ferrera et al. |
| 6,551,340 | B1 | | 4/2003 | Konya et al. |
| 6,565,601 | B2 | | 5/2003 | Wallace et al. |
| 6,589,230 | B2 | | 7/2003 | Gia et al. |
| 6,589,236 | B2 | | 7/2003 | Wheelock et al. |
| 6,592,566 | B2 | | 7/2003 | Kipke et al. |
| 6,599,308 | B2 | | 7/2003 | Amplatz |
| 6,605,101 | B1 | | 8/2003 | Schaefer et al. |
| 6,613,037 | B2 | | 9/2003 | Khosravi et al. |
| 6,623,493 | B2 | | 9/2003 | Wallace et al. |
| 6,623,508 | B2 | | 9/2003 | Shaw et al. |
| 6,635,069 | B1 | | 10/2003 | Teoh et al. |
| 6,638,291 | B1 | | 10/2003 | Ferrera et al. |
| 6,656,173 | B1 | | 12/2003 | Palermo |

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 6,656,201 | B2 | 12/2003 | Ferrera et al. |
| 6,656,206 | B2 | 12/2003 | Corcoran et al. |
| 6,660,020 | B2 | 12/2003 | Wallace et al. |
| 6,676,971 | B2 | 1/2004 | Goupil et al. |
| 6,682,546 | B2 | 1/2004 | Amplatz |
| 6,699,484 | B2 | 3/2004 | Whitmore et al. |
| 6,723,108 | B1 | 4/2004 | Jones et al. |
| 6,730,108 | B2 | 5/2004 | Van Tassel et al. |
| 6,764,500 | B1 | 7/2004 | Muijs Van De Moer et al. |
| 6,790,218 | B2 | 9/2004 | Jayaraman |
| 6,872,218 | B2 | 3/2005 | Kurz et al. |
| 6,921,410 | B2 | 7/2005 | Porter |
| 6,949,113 | B2 | 9/2005 | Van Tassel et al. |
| 6,953,468 | B2 | 10/2005 | Jones et al. |
| 6,974,862 | B2 | 12/2005 | Ringeisen et al. |
| 6,979,344 | B2 | 12/2005 | Jones et al. |
| 6,994,717 | B2 | 2/2006 | Konya et al. |
| 6,997,918 | B2 | 2/2006 | Soltesz et al. |
| 7,011,677 | B2 | 3/2006 | Wallace et al. |
| 7,033,348 | B2 | 4/2006 | Alfano et al. |
| 7,049,348 | B2 | 5/2006 | Evans et al. |
| 7,070,608 | B2 | 7/2006 | Kurz et al. |
| 7,166,133 | B2 | 1/2007 | Evans et al. |
| 7,169,168 | B2 | 1/2007 | Muijs Van De Moer et al. |
| 7,179,276 | B2 | 2/2007 | Barry et al. |
| 7,182,774 | B2 | 2/2007 | Barry et al. |
| 7,214,765 | B2 | 5/2007 | Ringeisen et al. |
| 7,294,123 | B2 | 11/2007 | Jones et al. |
| 7,316,701 | B2 | 1/2008 | Ferrera et al. |
| 7,323,000 | B2 | 1/2008 | Monstdt et al. |
| 7,326,225 | B2 | 2/2008 | Ferrera et al. |
| 7,331,981 | B2 | 2/2008 | Cates et al. |
| 7,485,087 | B2 | 2/2009 | Burgard |
| 7,491,214 | B2 | 2/2009 | Greene, Jr. et al. |
| 7,601,165 | B2 | 10/2009 | Stone |
| 7,682,400 | B2 | 3/2010 | Zwirkoski |
| 7,819,898 | B2 | 10/2010 | Stone et al. |
| 7,931,671 | B2 | 4/2011 | Tenerz |
| 7,998,154 | B2 | 8/2011 | Manzo |
| 8,177,809 | B2 | 5/2012 | Mavani et al. |
| 8,206,416 | B2 | 6/2012 | Mavani et al. |
| 8,221,451 | B2 | 7/2012 | Mavani et al. |
| 8,377,094 | B2 | 2/2013 | Mavani et al. |
| 2002/0026210 | A1 | 2/2002 | Abdel-Gawwad |
| 2002/0058960 | A1 | 5/2002 | Hudson et al. |
| 2002/0147457 | A1 | 10/2002 | Rousseau |
| 2003/0100920 | A1 | 5/2003 | Akin et al. |
| 2003/0220666 | A1 | 11/2003 | Mirigian et al. |
| 2004/0034366 | A1 | 2/2004 | van der Burg et al. |
| 2004/0044357 | A1 | 3/2004 | Gannoe et al. |
| 2004/0044358 | A1 | 3/2004 | Khosravi et al. |
| 2004/0044391 | A1 | 3/2004 | Porter |
| 2004/0122456 | A1 | 6/2004 | Saadat et al. |
| 2004/0186464 | A1 | 9/2004 | Mamayek et al. |
| 2004/0199175 | A1 | 10/2004 | Jaeger et al. |
| 2004/0225183 | A1 | 11/2004 | Michlitsch et al. |
| 2004/0236344 | A1 | 11/2004 | Monstadt et al. |
| 2004/0236348 | A1 | 11/2004 | Diaz et al. |
| 2004/0237970 | A1 | 12/2004 | Vournakis et al. |
| 2005/0033401 | A1 | 2/2005 | Cunniffe et al. |
| 2005/0049626 | A1 | 3/2005 | Bugard |
| 2005/0049628 | A1 | 3/2005 | Schweikert et al. |
| 2005/0070759 | A1 | 3/2005 | Armstrong |
| 2005/0090860 | A1 | 4/2005 | Paprocki |
| 2005/0090861 | A1 | 4/2005 | Porter |
| 2005/0113858 | A1 | 5/2005 | Deutsch |
| 2005/0155608 | A1 | 7/2005 | Pavcnik et al. |
| 2005/0159776 | A1 | 7/2005 | Armstrong |
| 2005/0182495 | A1 | 8/2005 | Perrone |
| 2005/0228448 | A1 | 10/2005 | Li |
| 2005/0240216 | A1 | 10/2005 | Jones et al. |
| 2005/0251200 | A1 | 11/2005 | Porter |
| 2005/0267528 | A1 | 12/2005 | Ginn et al. |
| 2005/0277981 | A1 | 12/2005 | Maahs et al. |
| 2005/0283187 | A1 | 12/2005 | Longson |
| 2006/0009797 | A1 | 1/2006 | Armstrong |
| 2006/0036282 | A1 | 2/2006 | Wahr et al. |
| 2006/0052822 | A1 | 3/2006 | Mirizzi et al. |
| 2006/0058834 | A1 | 3/2006 | Do et al. |
| 2006/0074447 | A2 | 4/2006 | Armstrong |
| 2006/0079929 | A1 | 4/2006 | Marks et al. |
| 2006/0122633 | A1 | 6/2006 | To et al. |
| 2006/0142797 | A1 | 6/2006 | Egnelov |
| 2006/0155303 | A1 | 7/2006 | Konya et al. |
| 2006/0200192 | A1 | 9/2006 | Fitz et al. |
| 2006/0206140 | A1 | 9/2006 | Shaolian et al. |
| 2006/0206196 | A1 | 9/2006 | Porter |
| 2006/0212055 | A1 | 9/2006 | Karabey et al. |
| 2006/0241687 | A1 | 10/2006 | Glaser et al. |
| 2006/0264698 | A1 | 11/2006 | Kondonis et al. |
| 2006/0265001 | A1 | 11/2006 | Marks et al. |
| 2006/0271099 | A1 | 11/2006 | Marks et al. |
| 2006/0282112 | A1 | 12/2006 | Griffin |
| 2007/0031508 | A1 | 2/2007 | Armstrong et al. |
| 2007/0083226 | A1 | 4/2007 | Buiser et al. |
| 2007/0088445 | A1 | 4/2007 | Patel et al. |
| 2007/0129757 | A1 | 6/2007 | Armstrong |
| 2007/0135842 | A1 | 6/2007 | Van de Moer et al. |
| 2007/0142859 | A1 | 6/2007 | Buiser et al. |
| 2007/0179507 | A1 | 8/2007 | Shah |
| 2007/0179527 | A1 | 8/2007 | Eskuri et al. |
| 2007/0185530 | A1 | 8/2007 | Chin-Chen et al. |
| 2007/0198059 | A1 | 8/2007 | Patel et al. |
| 2007/0233278 | A1 | 10/2007 | Armstrong |
| 2007/0244502 | A1 | 10/2007 | Deutsch |
| 2007/0276121 | A1 | 11/2007 | Westergom et al. |
| 2008/0004657 | A1 | 1/2008 | Obermiller et al. |
| 2008/0009781 | A1 | 1/2008 | Anwar et al. |
| 2008/0015635 | A1 | 1/2008 | Olsen et al. |
| 2008/0015636 | A1 | 1/2008 | Olsen et al. |
| 2008/0027477 | A1 | 1/2008 | Obermiller et al. |
| 2008/0039547 | A1 | 2/2008 | Khatri et al. |
| 2008/0039548 | A1 | 2/2008 | Zavatsky et al. |
| 2008/0051824 | A1* | 2/2008 | Gertner ..... 606/192 |
| 2008/0051831 | A1 | 2/2008 | Deal et al. |
| 2008/0071310 | A1 | 3/2008 | Hoffman et al. |
| 2008/0245374 | A1 | 10/2008 | Agnew |
| 2009/0054927 | A1 | 2/2009 | Agnew |
| 2009/0099647 | A1 | 4/2009 | Glimsdale et al. |
| 2009/0281557 | A1 | 11/2009 | Sander et al. |
| 2010/0076463 | A1 | 3/2010 | Mavani et al. |
| 2010/0087854 | A1 | 4/2010 | Stopek et al. |
| 2010/0185234 | A1 | 7/2010 | Fortson et al. |
| 2011/0130769 | A1 | 6/2011 | Boebel et al. |
| 2011/0282368 | A1 | 11/2011 | Swayze et al. |
| 2012/0016412 | A1 | 1/2012 | Mavani et al. |
| 2012/0035644 | A1 | 2/2012 | Eskaros et al. |
| 2012/0116447 | A1 | 5/2012 | Stanley et al. |
| 2012/0323271 | A1 | 12/2012 | Obermiller et al. |
| 2013/0006283 | A1 | 1/2013 | Carrison et al. |

FOREIGN PATENT DOCUMENTS

| | | |
|---|---|---|
| JP | 2008-543504 | 12/2008 |
| WO | 89/11301 | 11/1989 |
| WO | 00/74576 | 12/2000 |
| WO | 2004/112864 | 12/2004 |
| WO | 2005/070302 | 8/2005 |
| WO | 2006/119256 | 11/2006 |
| WO | 2006/130213 | 12/2006 |
| WO | 2007/002260 | 1/2007 |
| WO | 2008/112740 | 9/2008 |
| WO | 2009/124144 | 4/2009 |
| WO | 2009/124148 | 4/2009 |
| WO | 2009/146369 A1 | 12/2009 |
| WO | 2010/028300 | 3/2010 |
| WO | 2012/050836 | 4/2012 |
| WO | 2012-050836 | 4/2012 |
| WO | 2012/174468 A1 | 12/2012 |
| WO | 2012/174469 A2 | 12/2012 |

OTHER PUBLICATIONS

Written Opinion, in connection with International Patent application No. PCT/US2012/042805, Nov. 28, 2012, (pp. 1-6).

(56) **References Cited**

OTHER PUBLICATIONS

Patent Examination Report No. 1 issued by the Australian Patent Office for Austrian Patent Application No. 2009289474, (Dec. 11, 2014) pp. 1-5.

First Examination Report issued by the Canadian Patent Office for Patent Application No. 2,720,206, (May 19, 2015) pp. 1-4.

Supplementary European Search Report issued by the European Patent Office for Application No. 12801043.6, (Jan. 15, 2015) pp. 1-7.

Extended European Search Report issued by the European Patent Office for Application No. 12800217.7, (Mar. 24, 2015) pp. 1-6.

International Search Report Issued by WIPO for PCT Application Serial No. PCT/US14/043261, (Dec. 23, 2014) pp. 1-4.

Written Opinion of the International Searching Authority issued by WIPO for PCT Application Serial No. PCT/US14/043261, (Dec. 23, 2014) pp. 1-6.

Patent Examination Report No. 1, Australian Patent Application No. 2009289474 issued on related matter (Dec. 11, 2014) pp. 1-5.

First Examination Report, Canadian Patent Application No. 2,720,206, issued on related matter, (May 19, 2015) pp. 1-4.

Supplementary European Search Report issued by the European Patent Office for Application No. 12801043.6, issued on related matter, (Jan. 15, 2015) pp. 1-7.

European Search Report issued by the European Patent Office for Application No. 09728360.0, issued on related matter (Apr. 4, 2011) pp. 1-5.

Extended European Search Report, European Patent Application No. 12800217.7, issued on related matter, (Mar. 24, 2015) pp. 1-6.

Partial Search Report, issued by the European Searching Authority for Application No. PCT/US2014/011663, issued on related matter, (May 9, 2014) pp. 1-3.

International Search Report, PCT Application No. PCT/US2012/042805, issued on related matter, (Nov. 28, 2012) pp. 1-5.

International Search Report, PCT Application Serial No. PCT/US14/043261, issued on related matter, (Dec. 23, 2014) pp. 1-4.

International Search Report, PCT Application Serial No. PCT/US14/043280, issued on related matter, (Nov. 17, 2014) pp. 1-7.

Written Opinion, PCT Patent Application No. PCT/US2012/042805, issued on related mater, (Nov. 28, 2012) pp. 1-6.

Written Opinion of the International Searching Authority, PCT Application Serial No. PCT/US14/043261, issued on related matter, (Dec. 23, 2014) pp. 1-6.

Written Opinion of the International Searching Authority, PCT Application Serial No. PCT/US14/043280, issued on related matter, (Nov. 17, 2014) pp. 1-9.

Champagne, et al., "Efficacy of Anal Fistula Plug in Closure of Cryptoglandular Fistulas: Long-Term Follow-Up", Diseases of the Colon & Rectum, Dis. Colon Rectum 2006; vol. 49, No. 12, pp. 1817-1821. (5 pages).

Draus, et al., "Enterocutaneous fistula: Are treatments improving?", Surgery, vol. 140, No. 4, Oct. 2006, pp. 570-578. (9 pages).

Farsi, et al., "A New Conservative Approach in the Treatment of Postoperative Digestive-Tract Fistulas. Mechanical Closure by a Balloon-Catheter", Minerva Chir, Feb. 2001; 56(1):31-9, article in Italian. (1 page translation).

Hollington, et al., "An 11-year Experience of Enterocutaneous Fistula", British Journal of Surgery 2004; 91: pp. 1646-1651. (6 pages).

Hyman, "Anorectal Abscess and Fistula", Primary Care: Clinics in Office Practice, vol. 26, Issue 1, Mar. 1999, pp. 69-80. (13 pages).

Jenkins, et al., "Single Operator Deployment of Vasoseal ES ®: The Experience of Skaggs Community Health Center", Sep. 1, 2004. (2 pages).

Lomis, et al., "Refractory Abdominal-Cutaneous Fistulas or Leaks: Percutaneous Management with a Collagen Plug", Journal of the American College of Surgeons, vol. 190, No. 5, May 2000, pp. 588-592. (5 pages).

Mclean, et al., "Enterocutaneous Fistulae: Interventional Radiologic Management," AJR 138:615-619, Apr. 1982. (5 pages).

Medeiros, et al., "Treatment of Postoperative Enterocutaneous Fistulas by High-Pressure Vacuum with a Normal Oral Diet", Digestive Surgery, 2004; 21, pp. 401-405. (5 pages).

O'Connor, et al., "Efficacy of Anal Fistula Plug in Closure of Crohn's Anorectal Fistulas," Diseases of the Colon & Rectum, Dis Colon Rectum, Oct. 2006, vol. 49: pp. 1569-1573. (5 pages).

Paul, et al., "Bronchopleural Fistula Repair During Clagett Closure Utilizing a Collagen Matrix Plug", Ann. Thorac. Surg. 2007, 83, pp. 1519-1521. (3 pages).

Sutra, "Fistula in Ano", Way2Ayurveda, www.way2ayurveda.com/fistulainano/index.html, printed Mar. 20, 2008. (3 pages).

Unknown Author, *Controlled Deployment for Confident Closure*, St. Jude.Medical (2009) pp. 1-3.

Unknown Author, *Datascope's Vasoseal Seen As Cost Effective Aid To Coronary Patients*, Gale, Cengage Learning (2008) pp. 1-3.

Unknown Author, *Practice Parameters for Treatment of Fistula-in-Ano*, The American Society of Colon and Rectal Surgeons, ASCRS Standards Practice Task Force, Dis Colon Rectum (Dec. 1996) pp. 1361-1362. (2 pages).

Von Koperen, et al., "Anal Fistula Plug for Closure of Difficult Anorectal.Fistula: A Prospective Study," Dis Colon Rectum 2007; 50, pp. 1-5. (5 pages).

Wexner, et al., "Practice Parameters for Treatment of Fistula—in—Ano-Supporting Documentation", Dis Colon Rectum, Dec. 1996, pp. 1363-1372. (10 pages).

Zagrodnik II, "Fistula-in-Ano", General Surgery—Colorectal, Mar. 12,.2007. (16 pages).

* cited by examiner

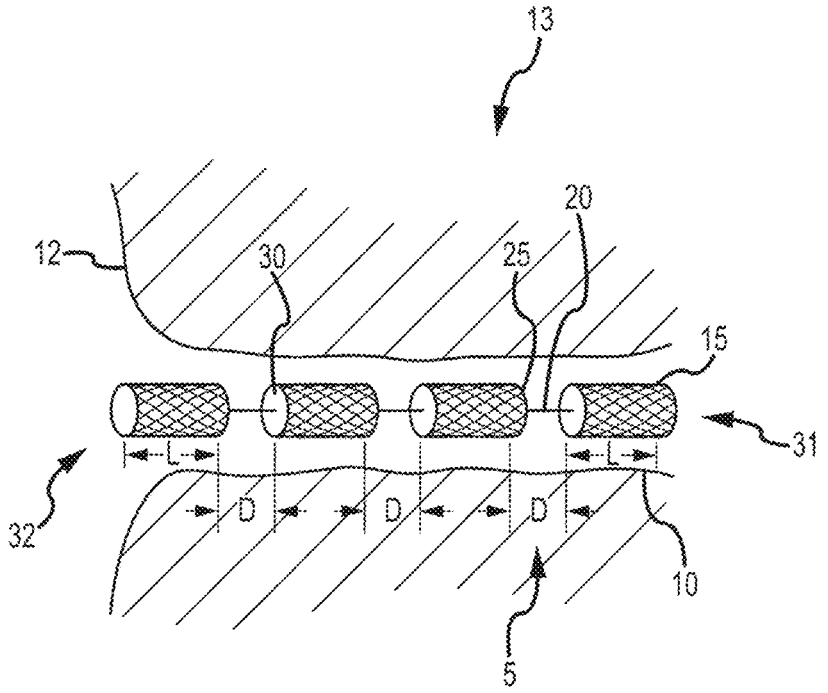
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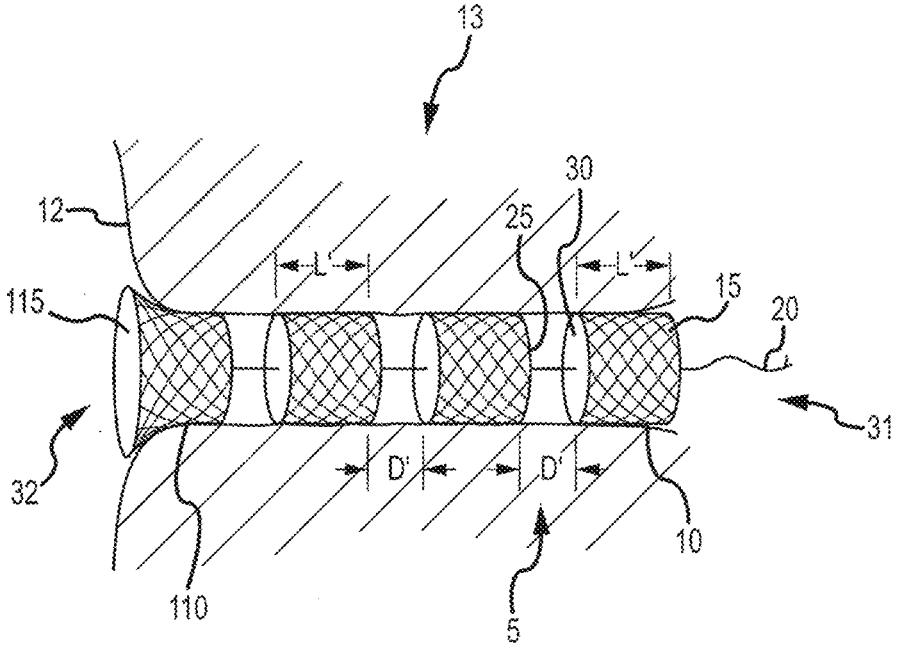
FIG.1A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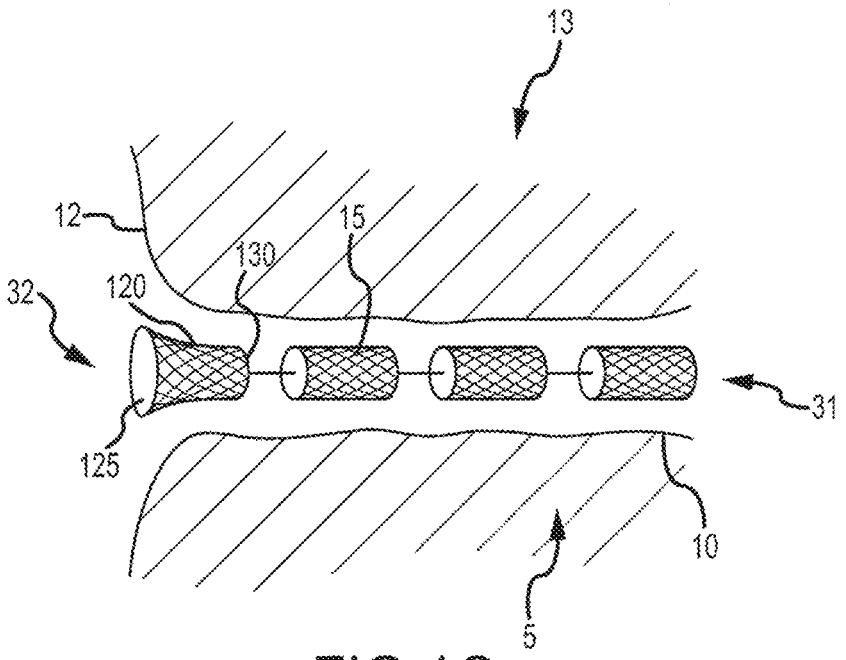



FIG.1C

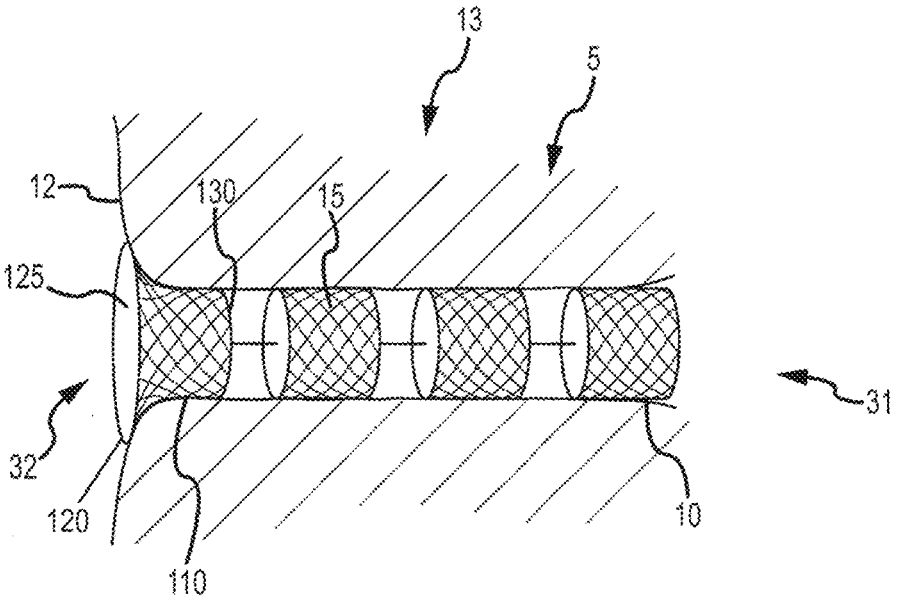
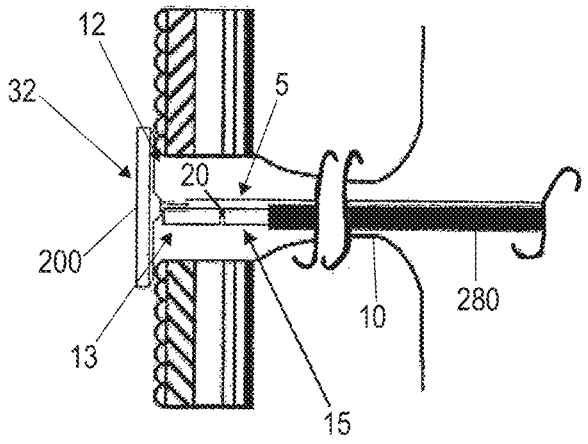



FIG.1D

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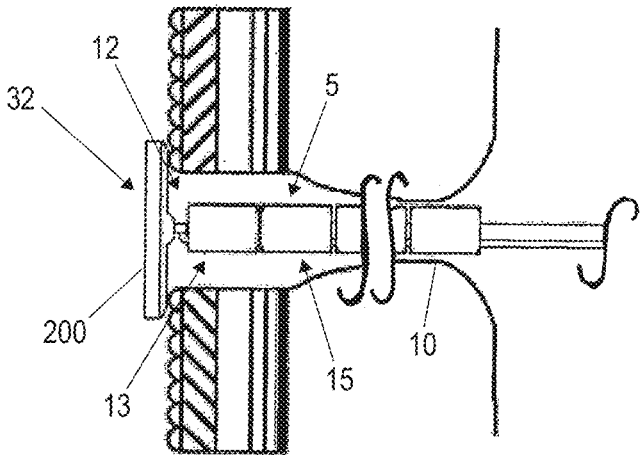


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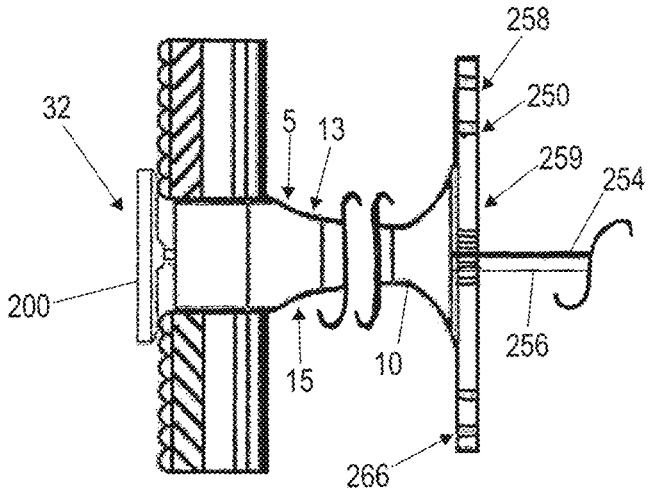
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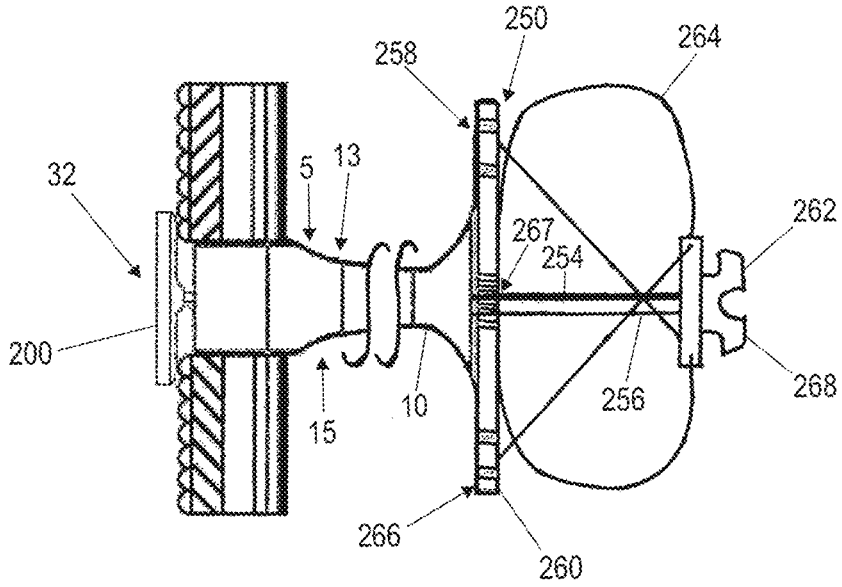
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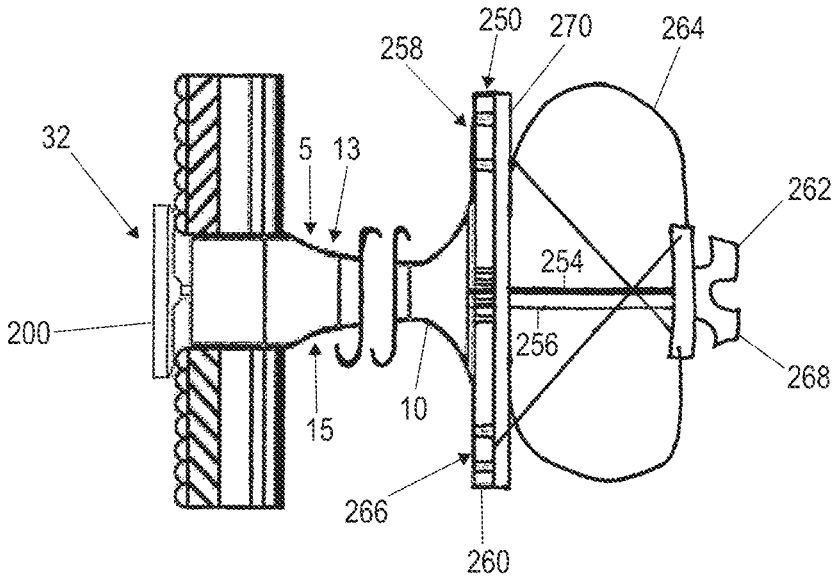
FIG. 2D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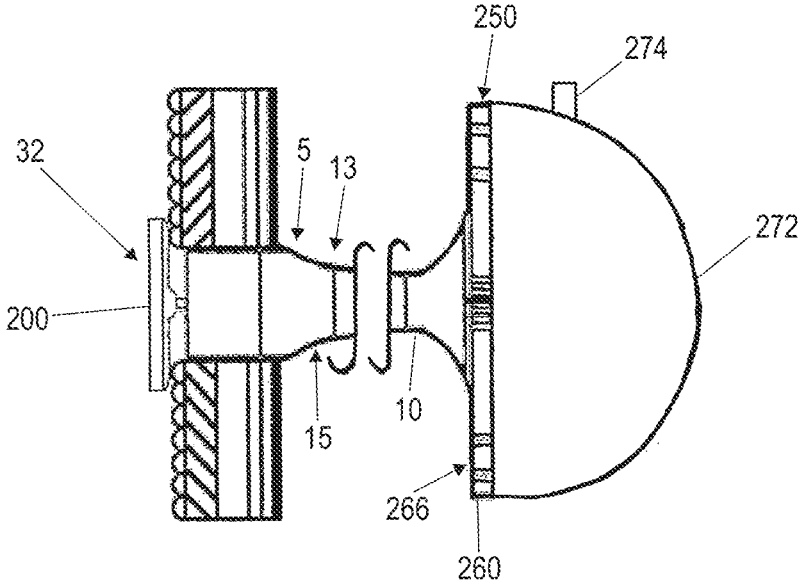
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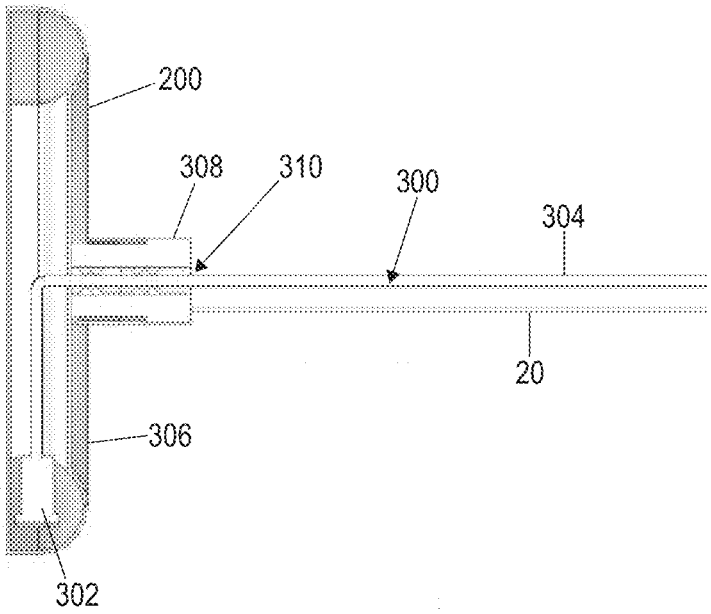
FIG. 2F

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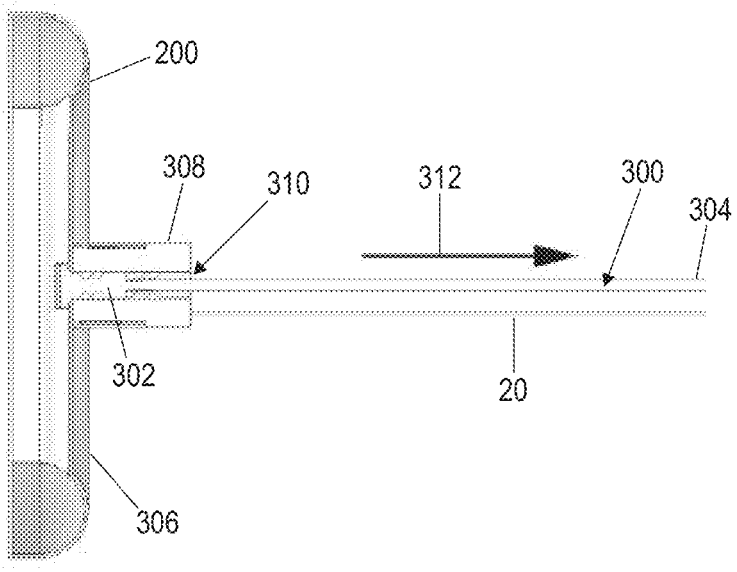



FIG. 3B

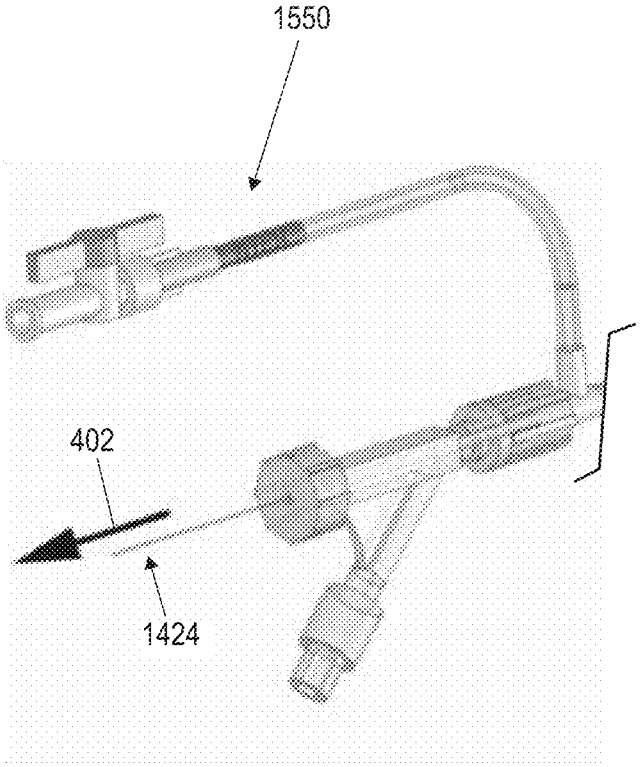
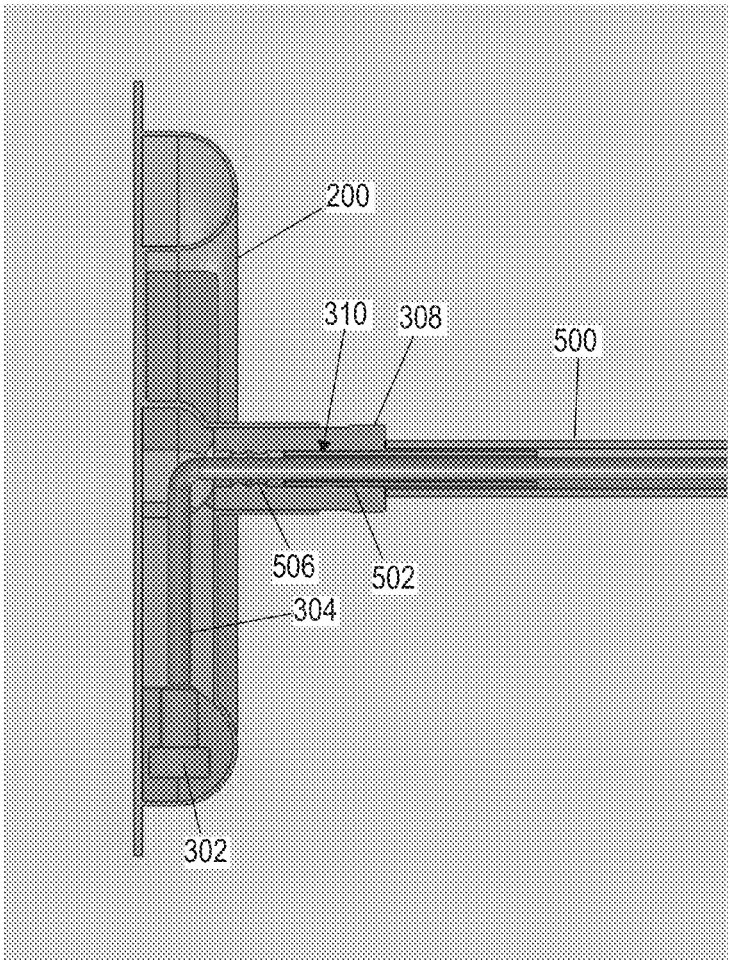



FIG. 4

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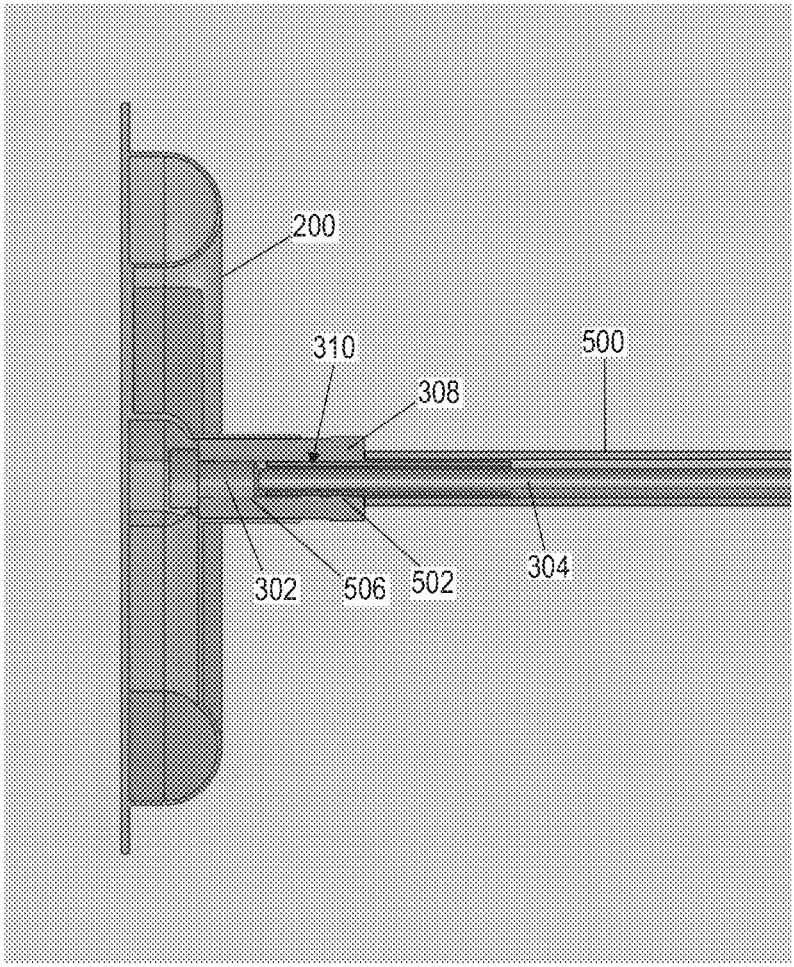
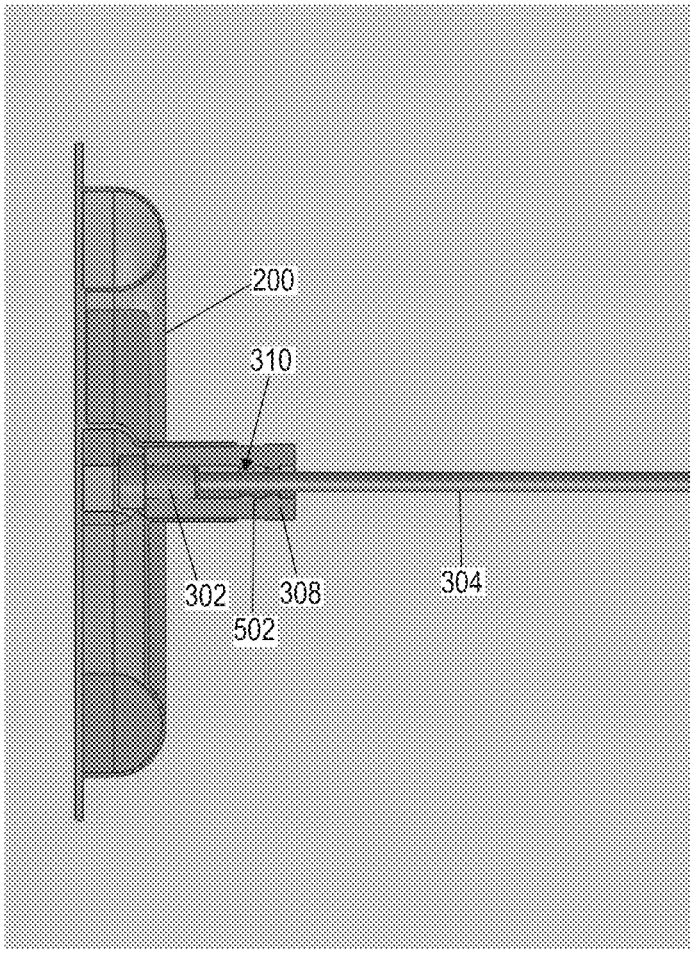



FIG. 5B

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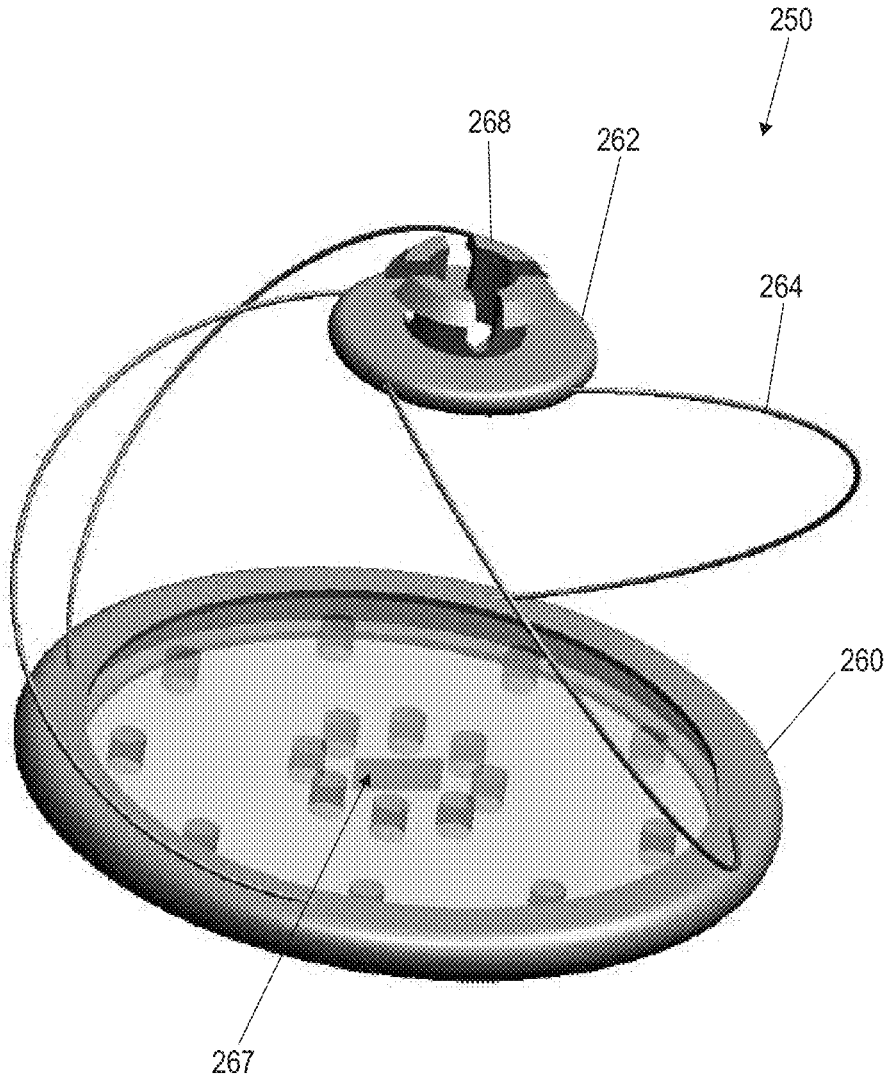


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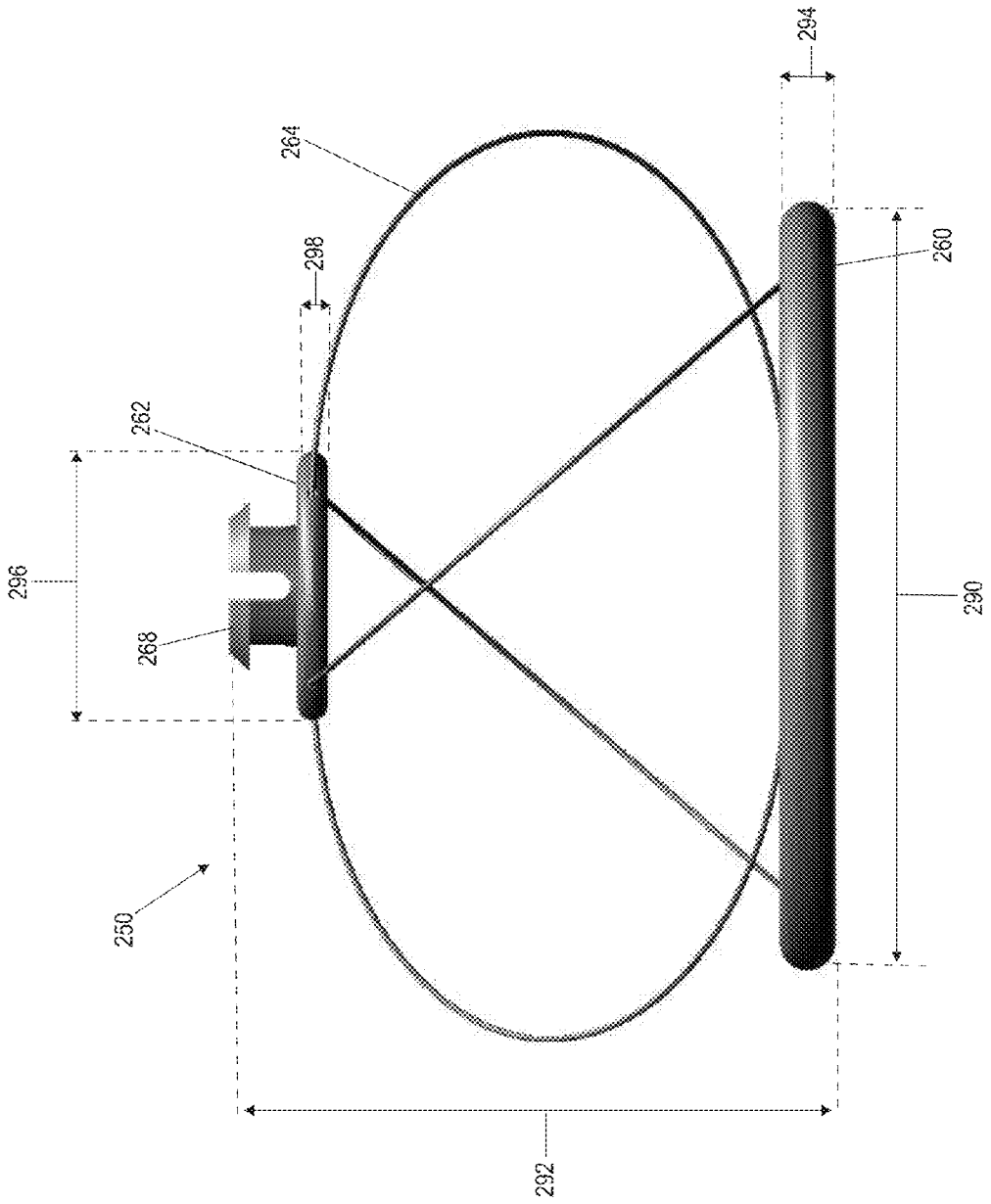


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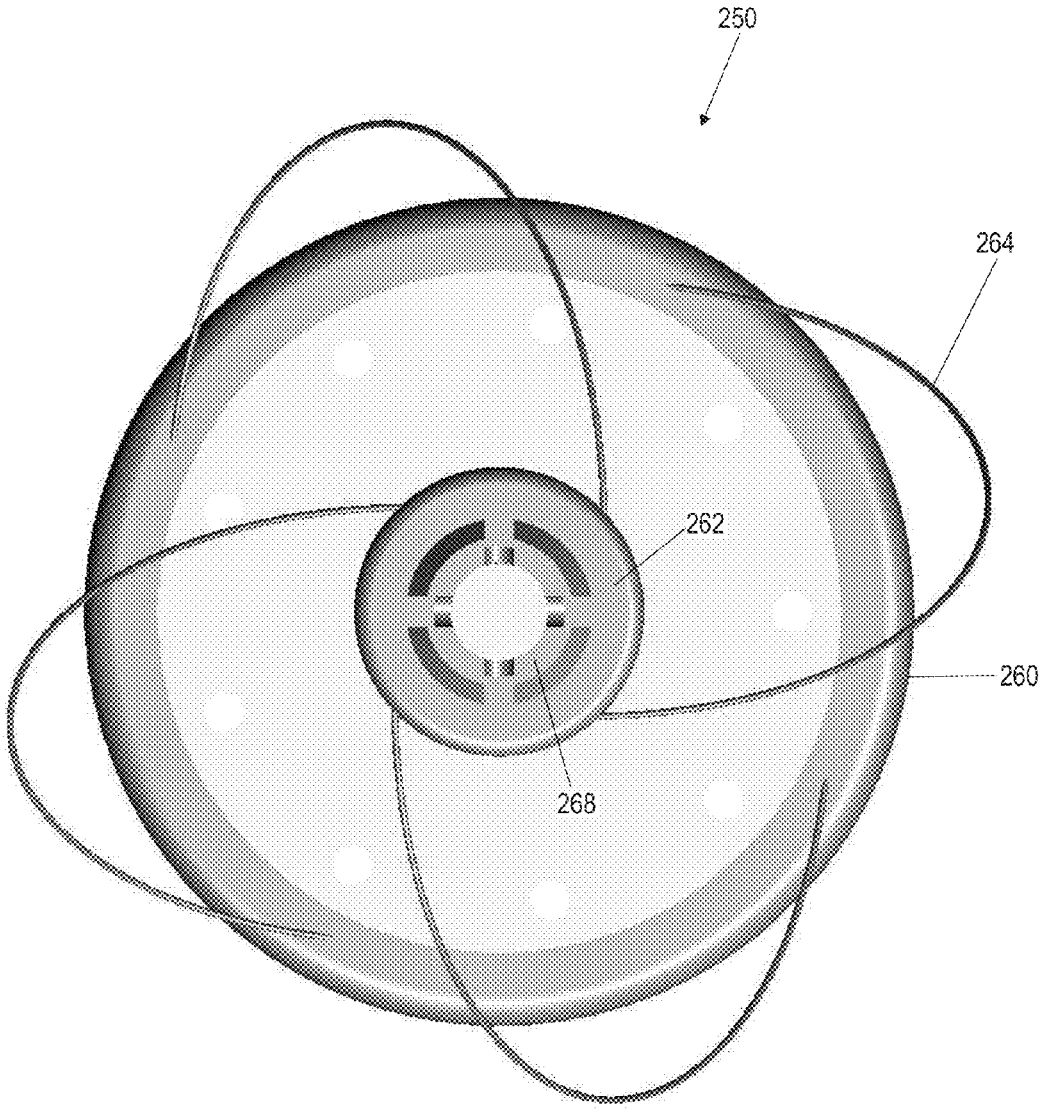
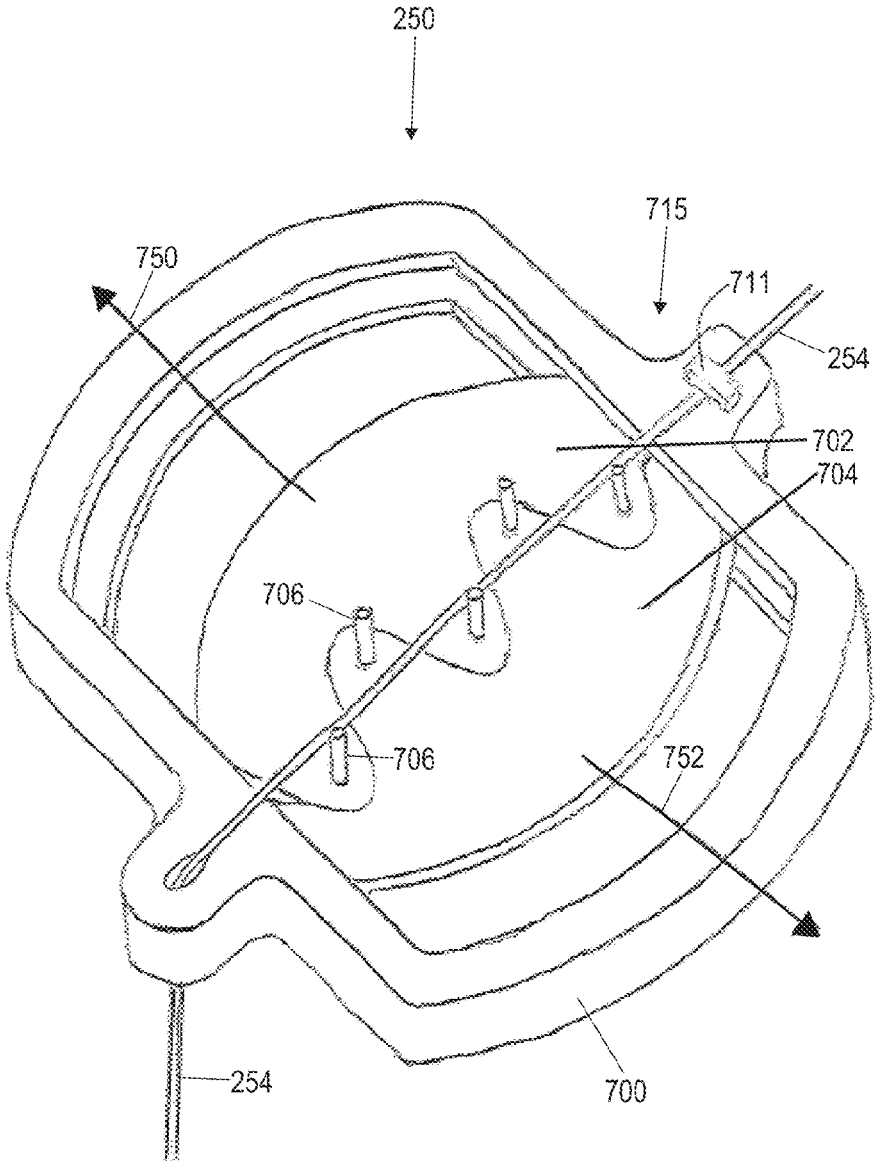



FIG. 6C

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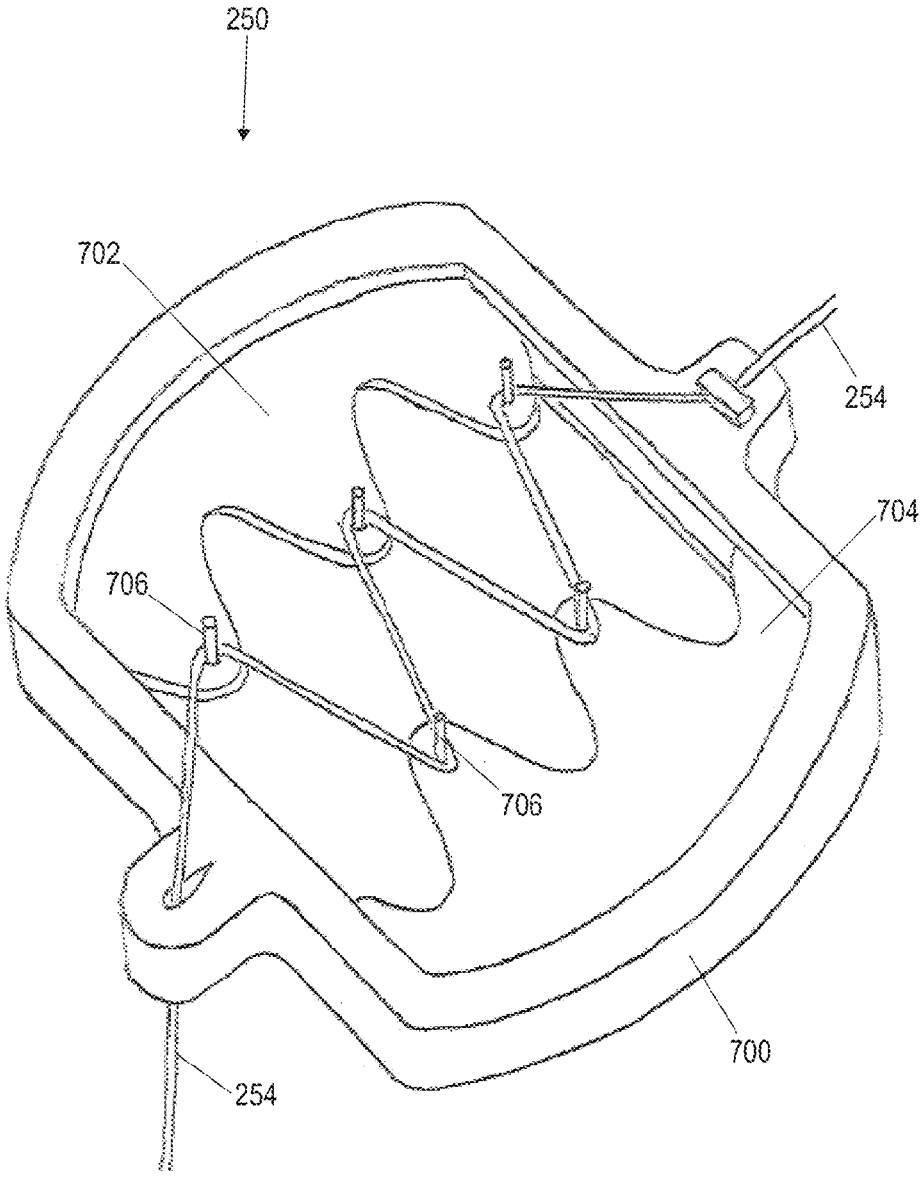



FIG. 7B

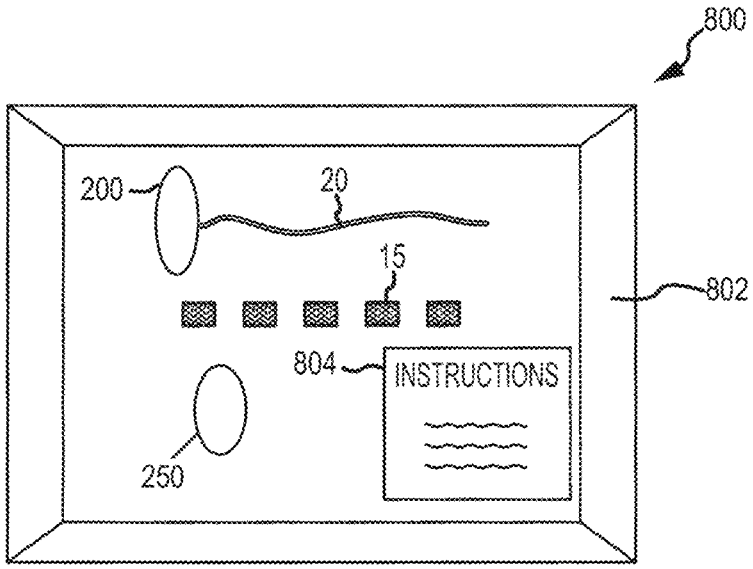
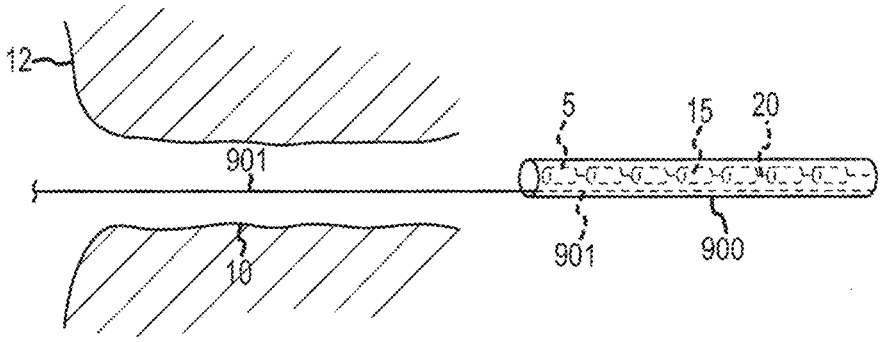



FIG. 8

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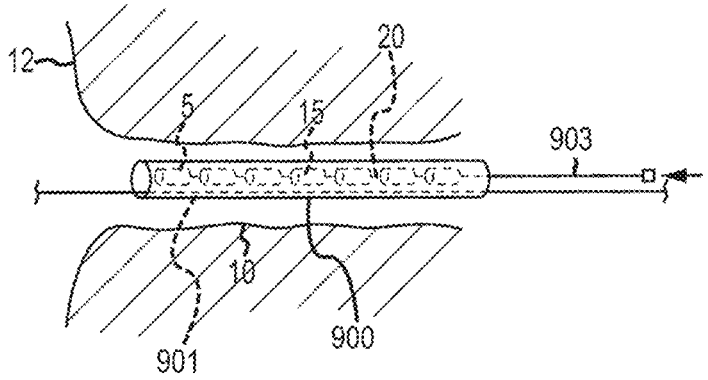


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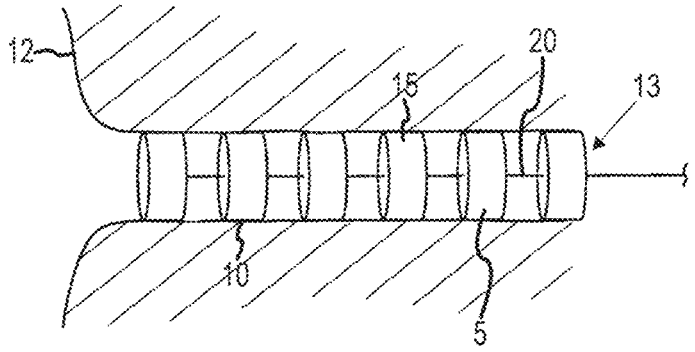



FIG. 9C

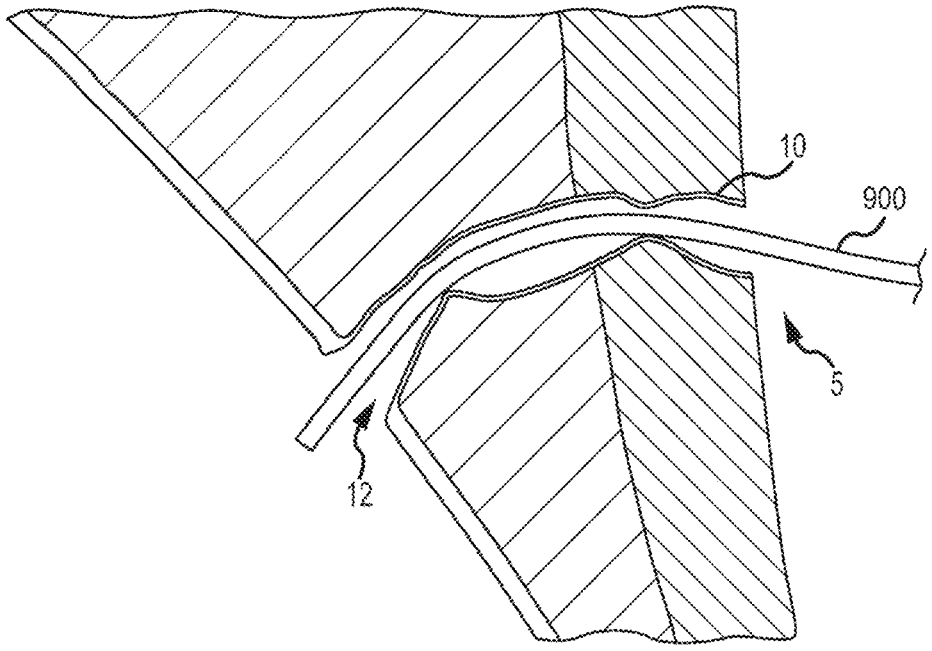
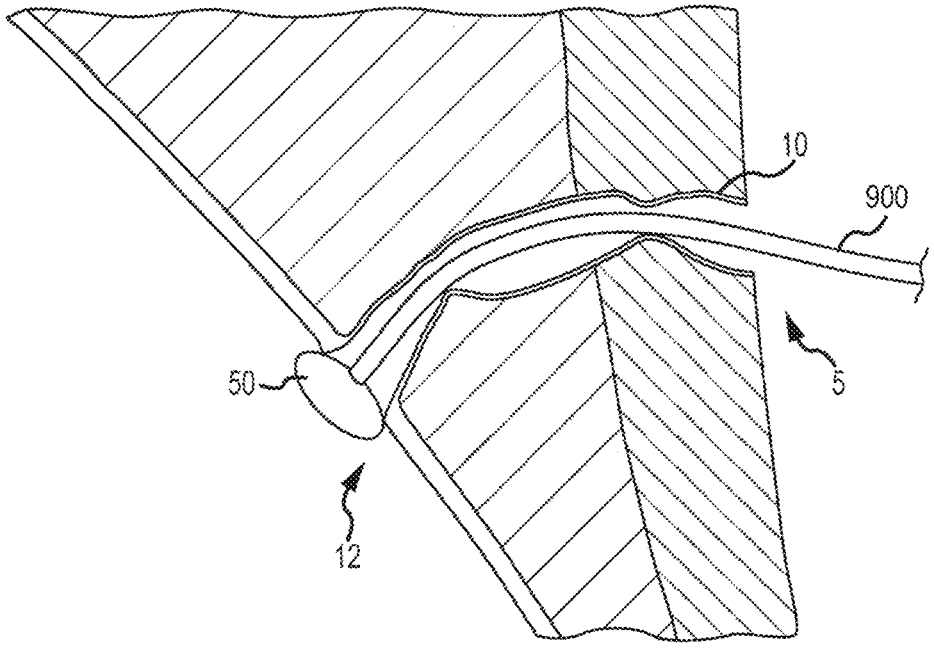



FIG. 10A

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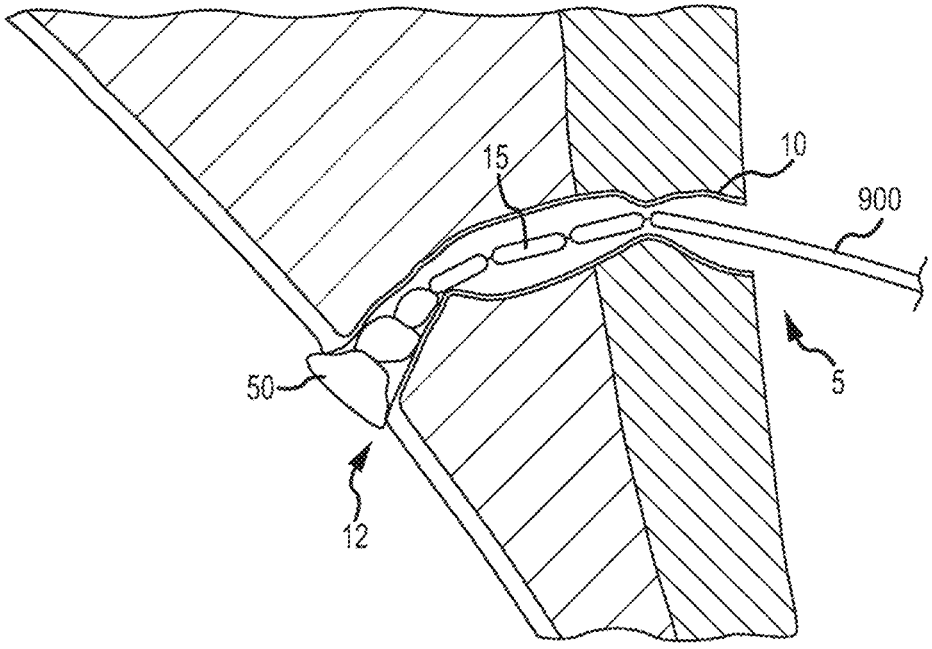


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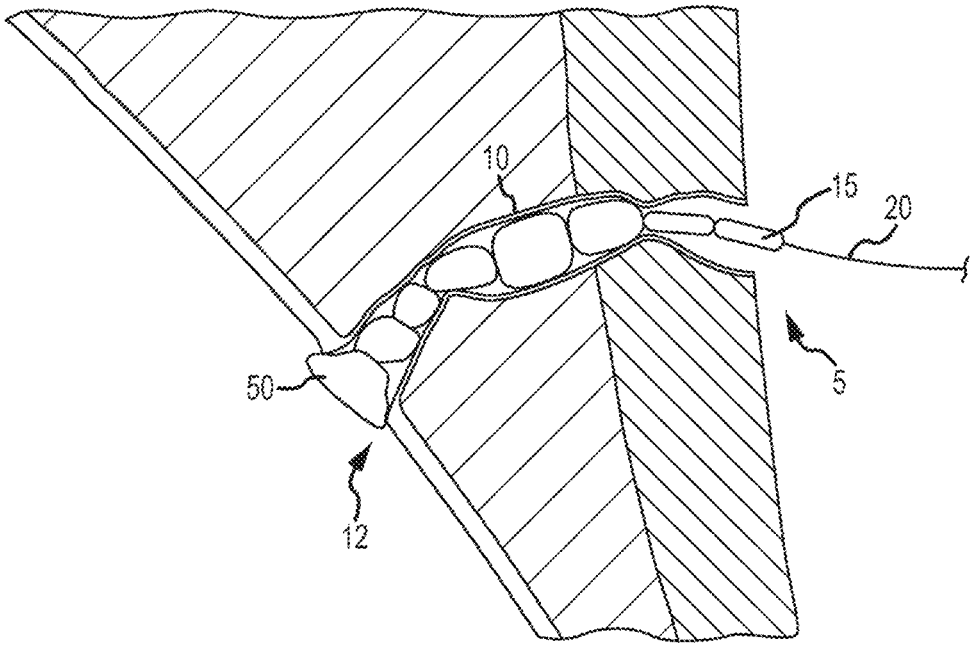


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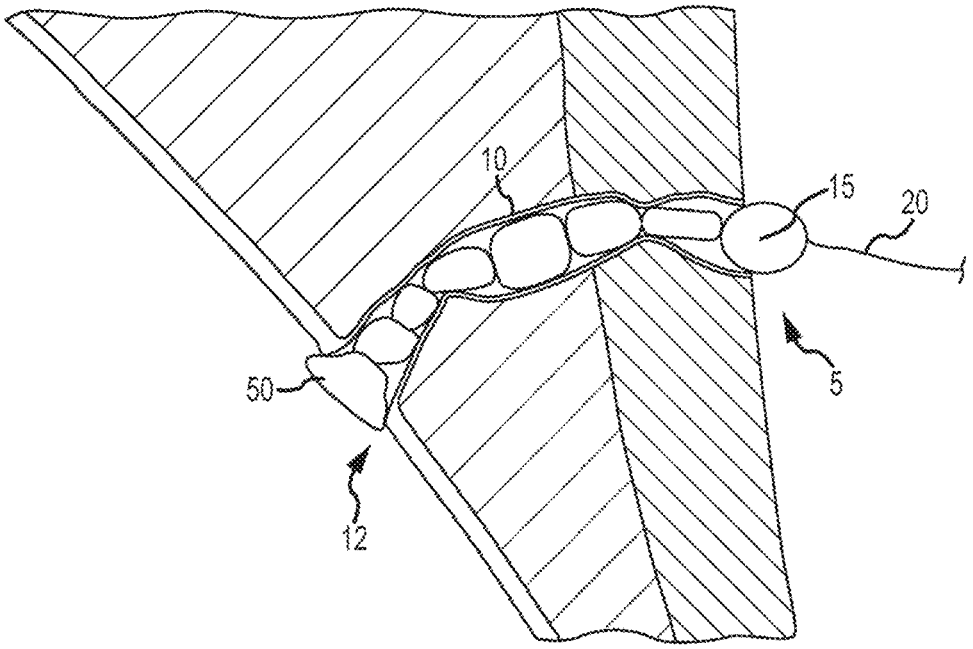


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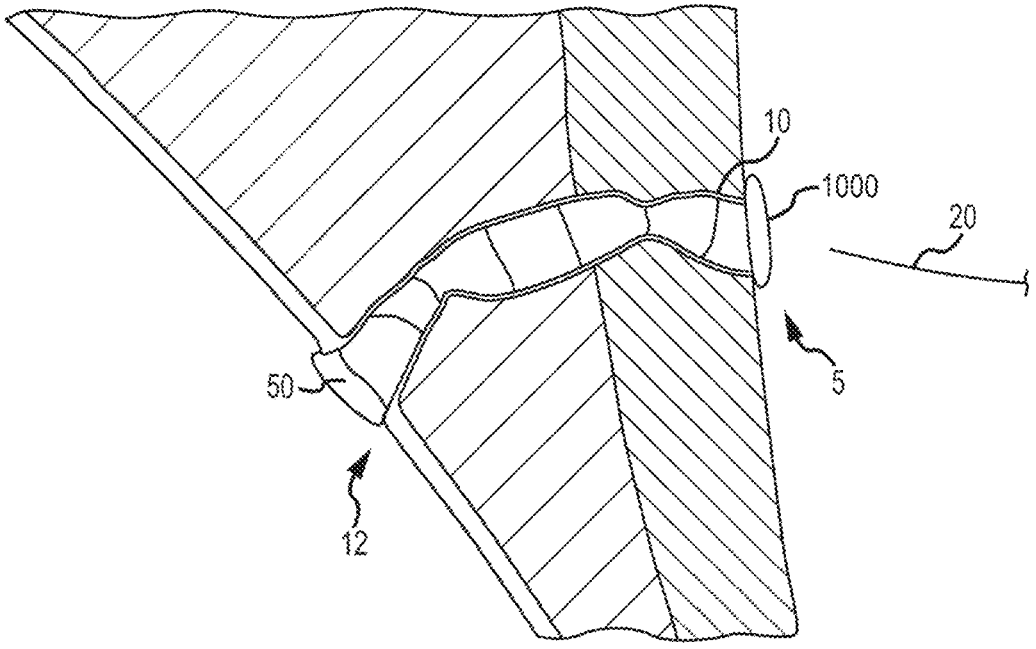


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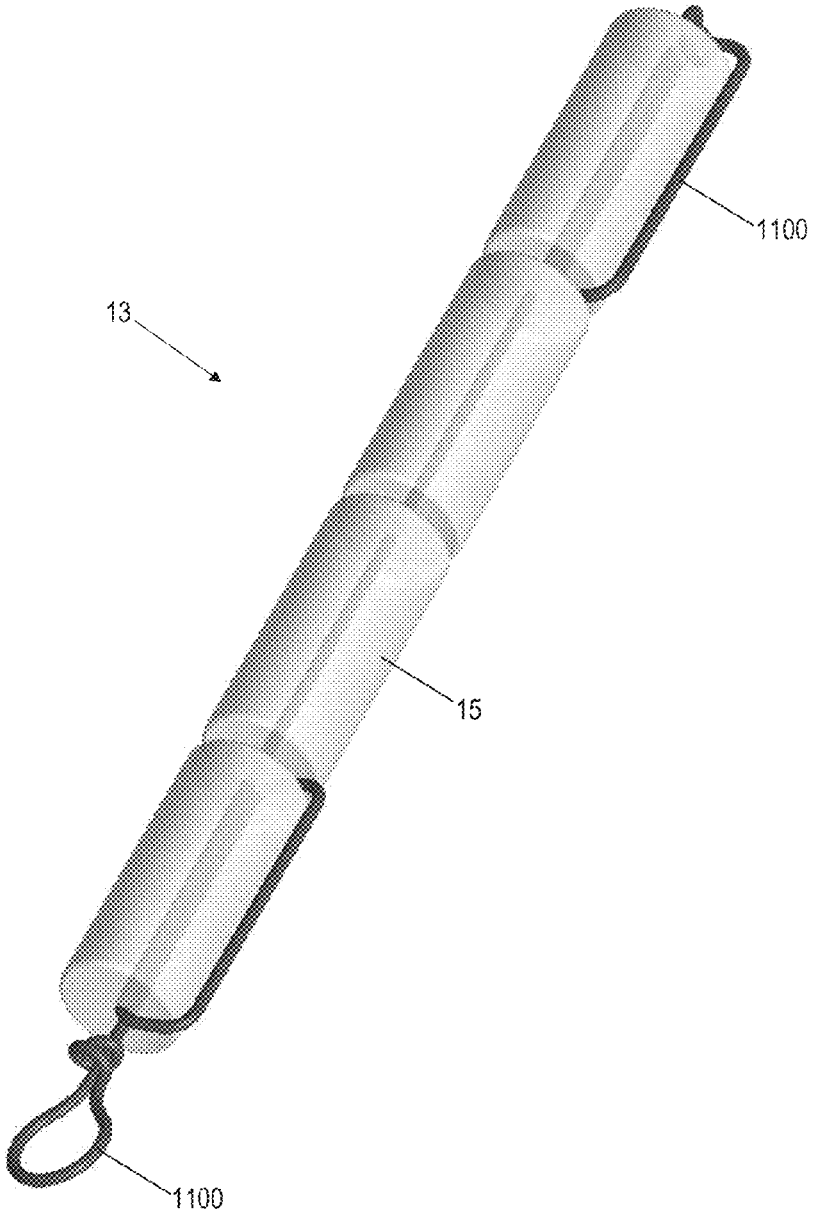


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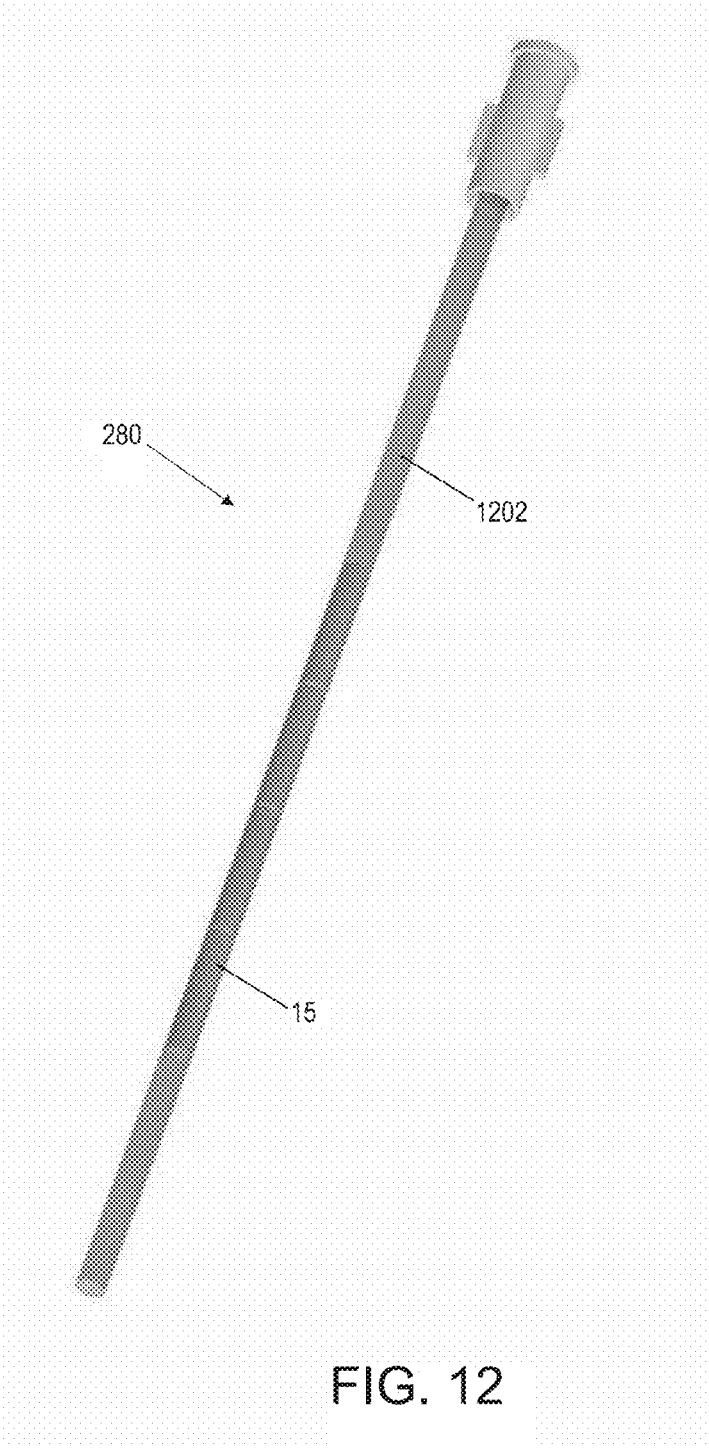
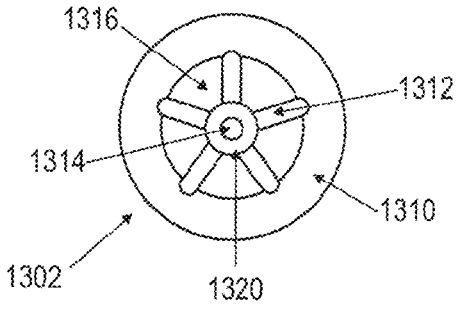



FIG. 12

FIG. 13A

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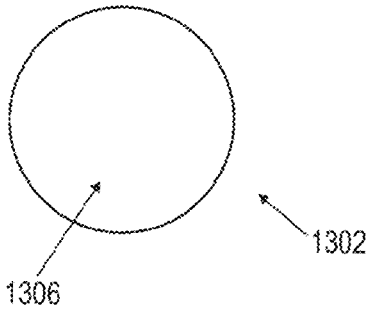


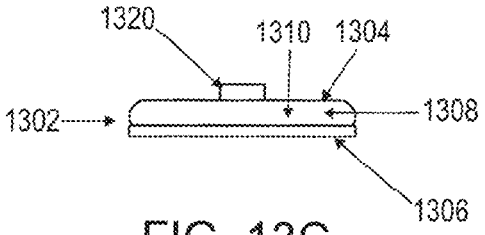


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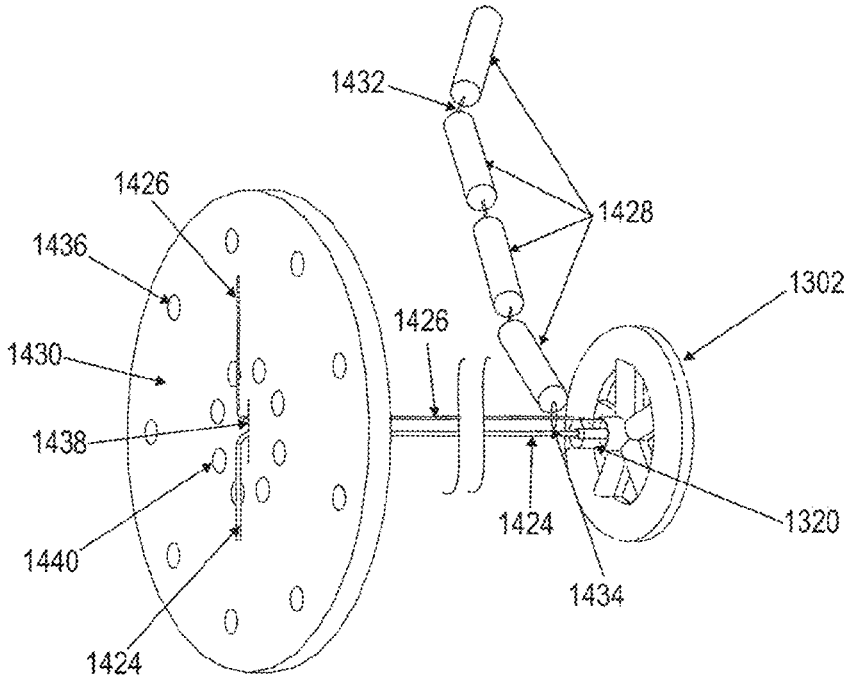


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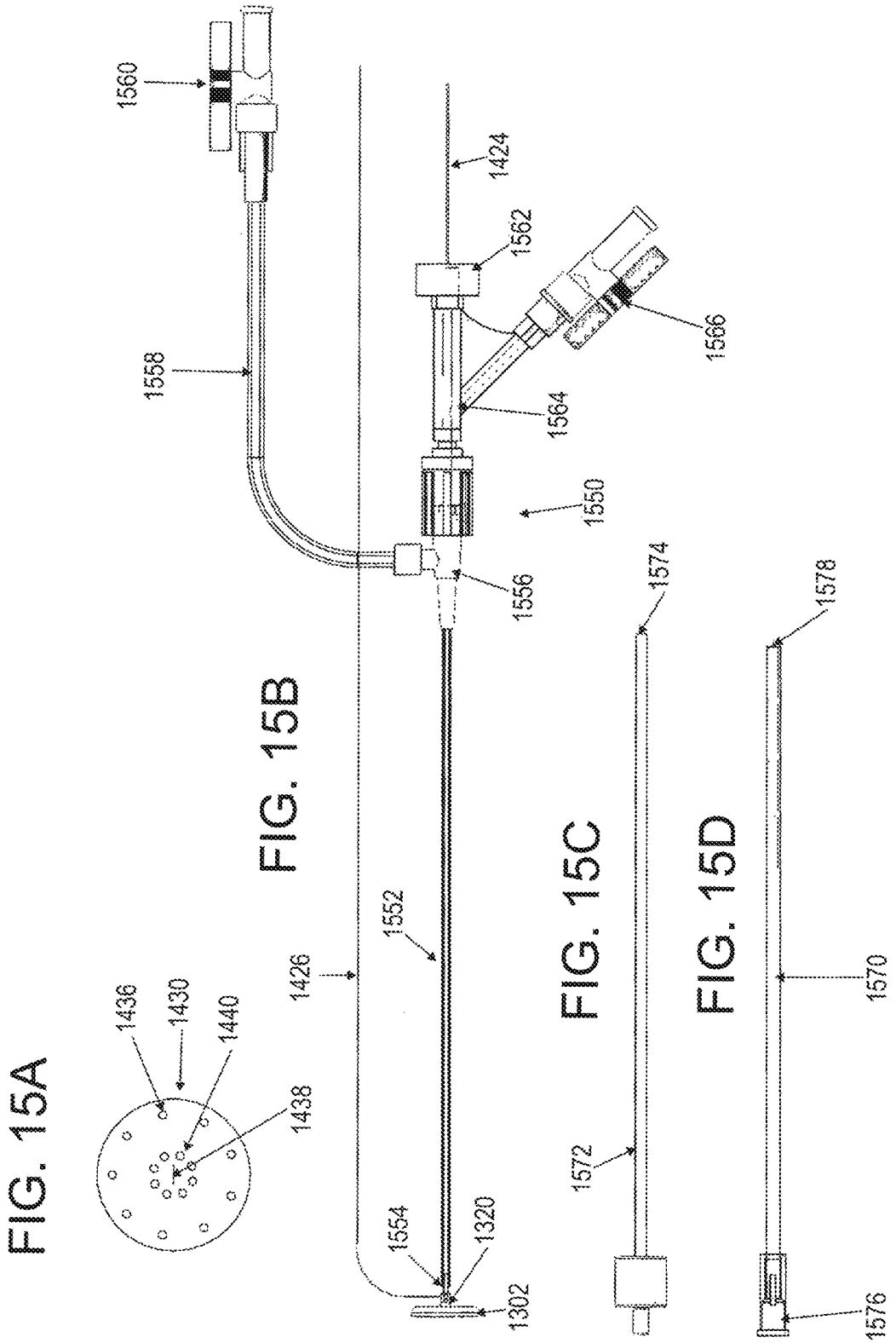
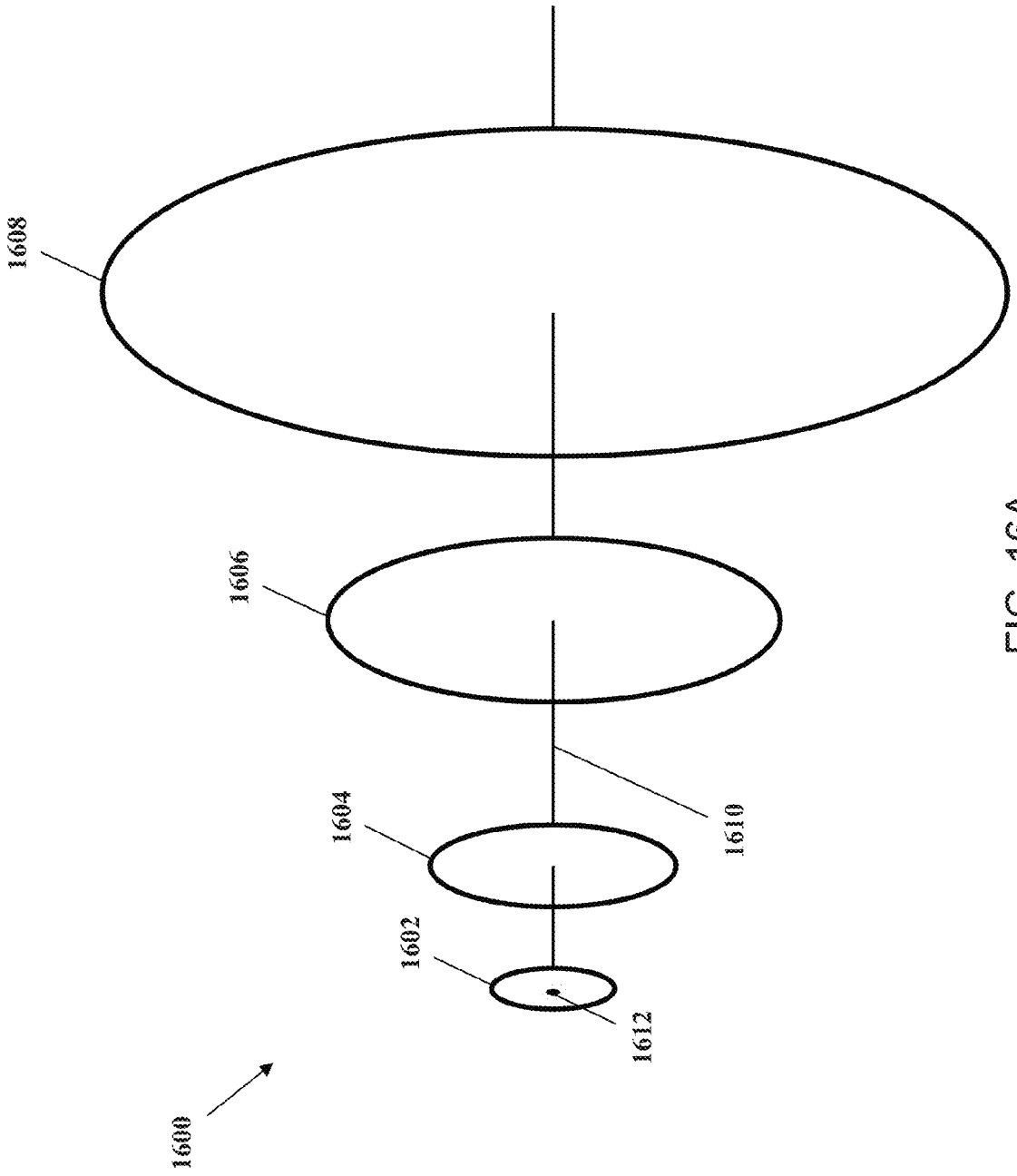



FIG. 15A

FIG. 15B

FIG. 15C

FIG. 15D

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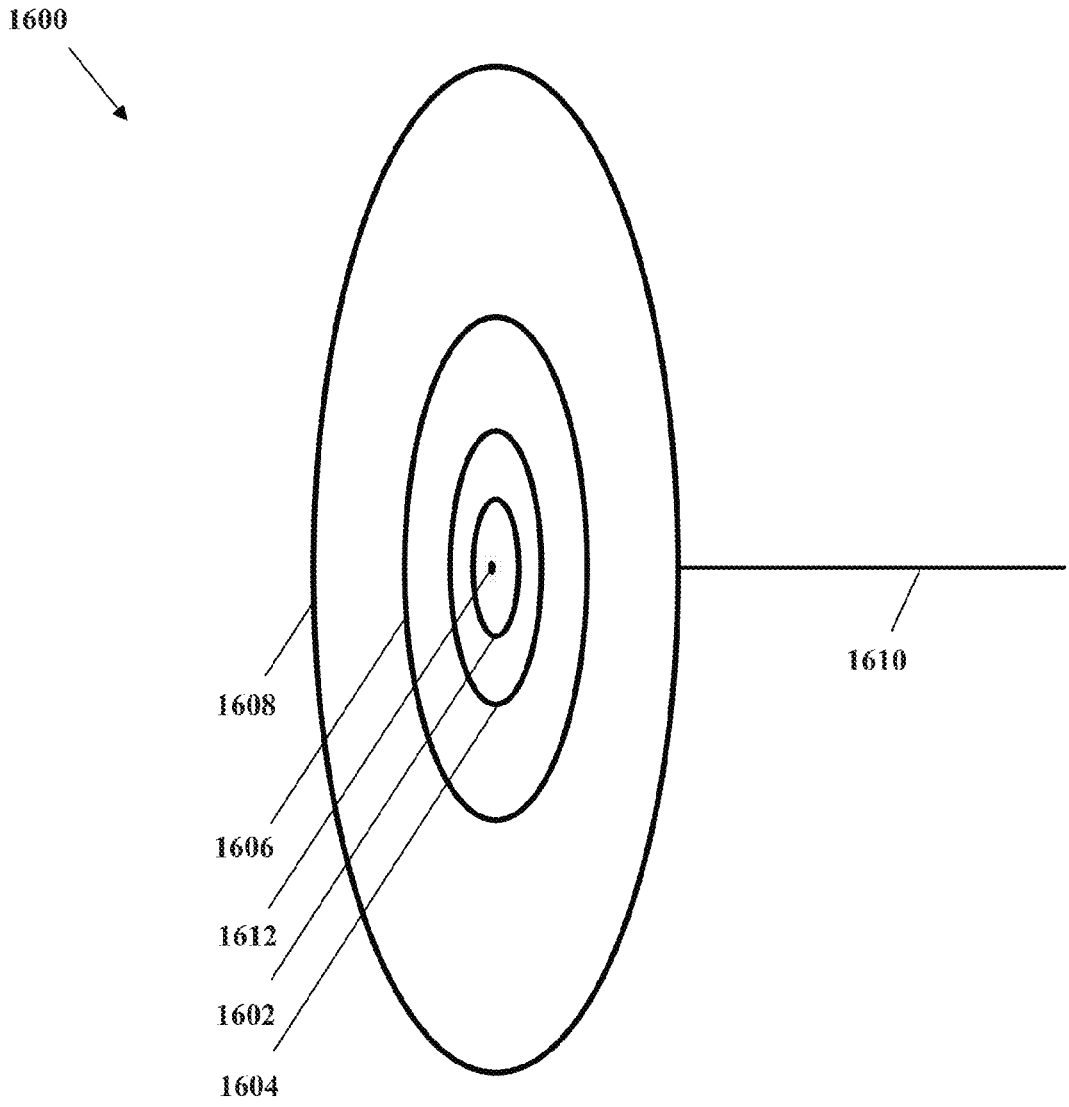


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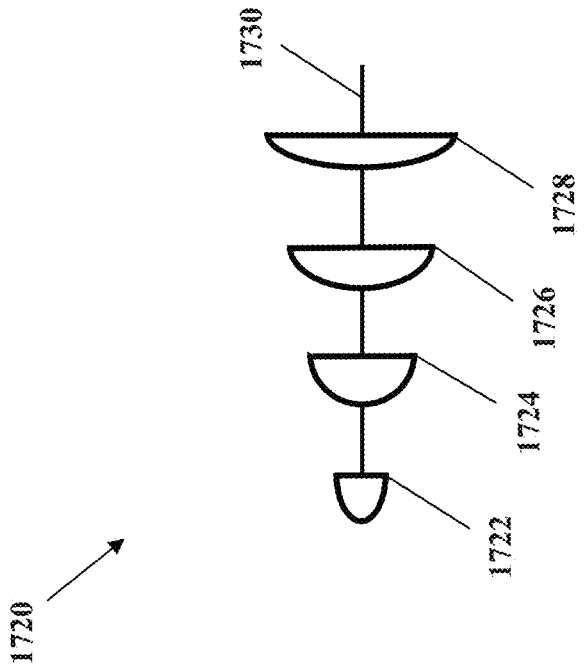


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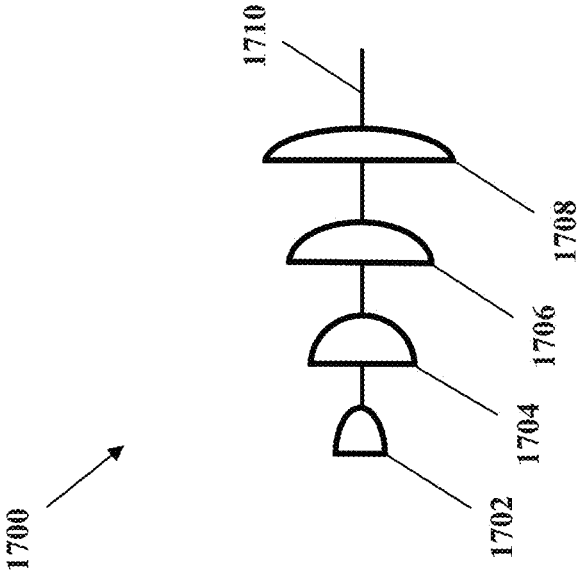


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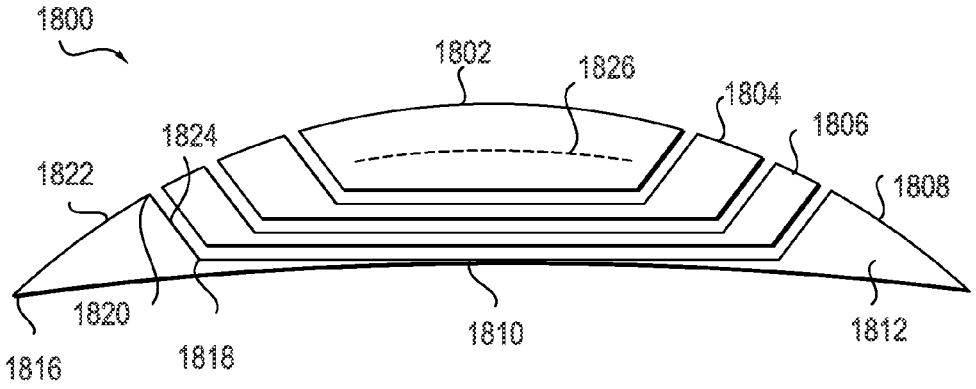
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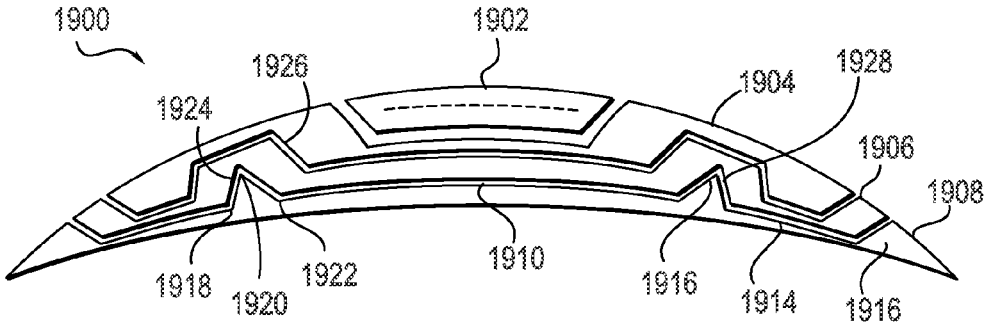
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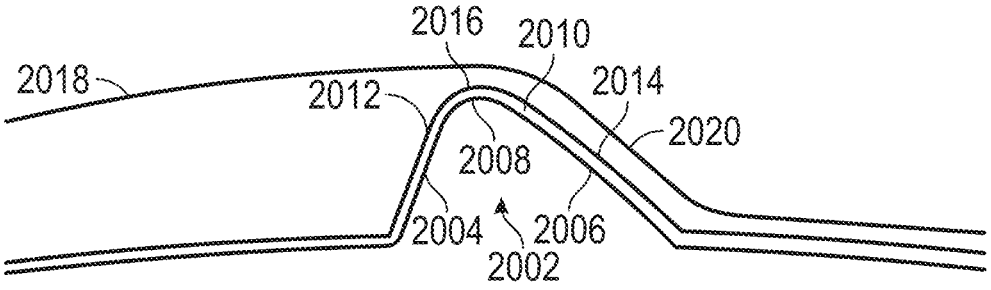


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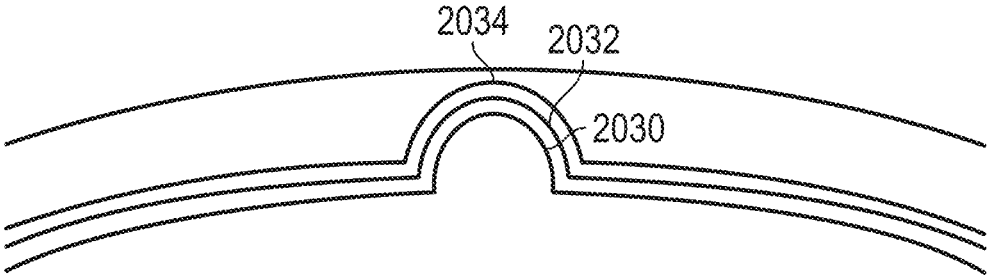


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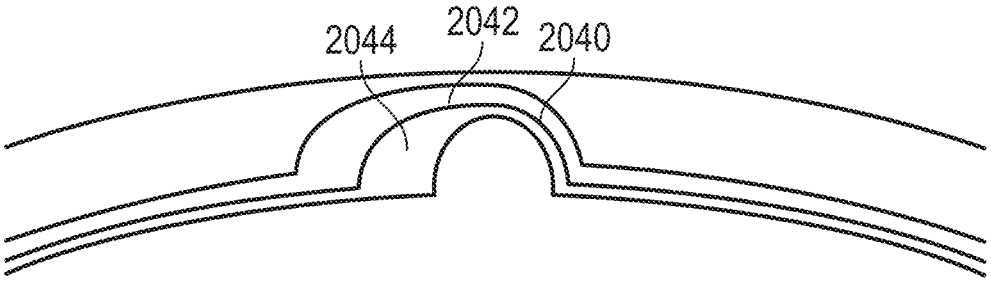


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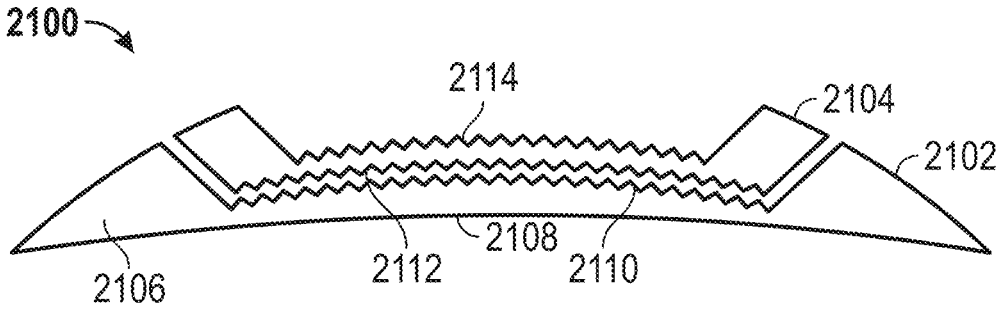
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FIG. 21

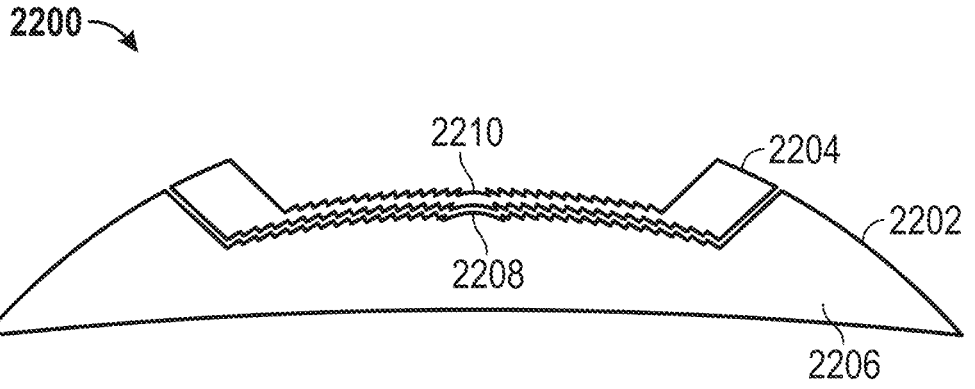
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FIG. 22

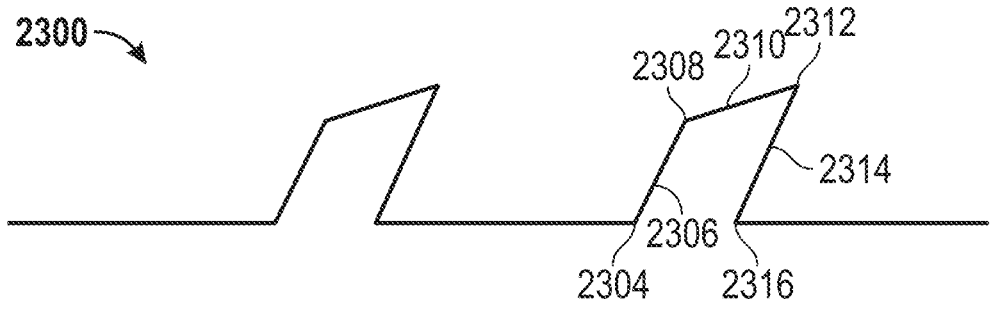


FIG. 23A

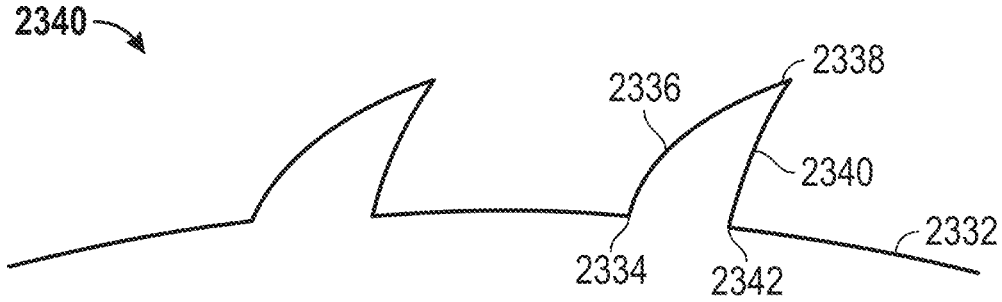


FIG. 23B

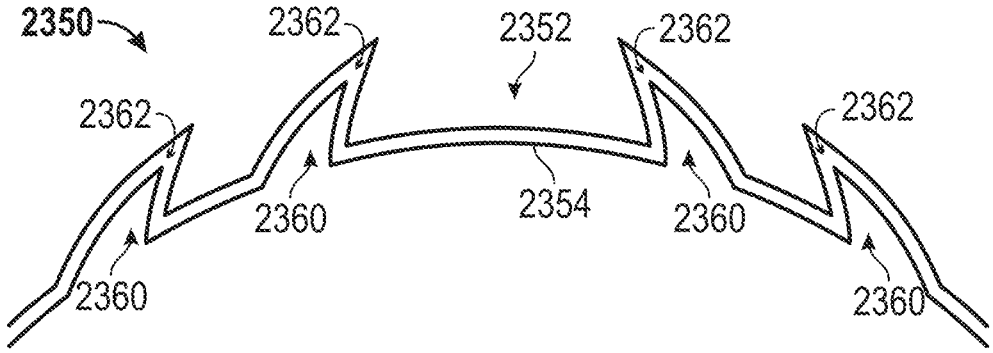


FIG. 23C

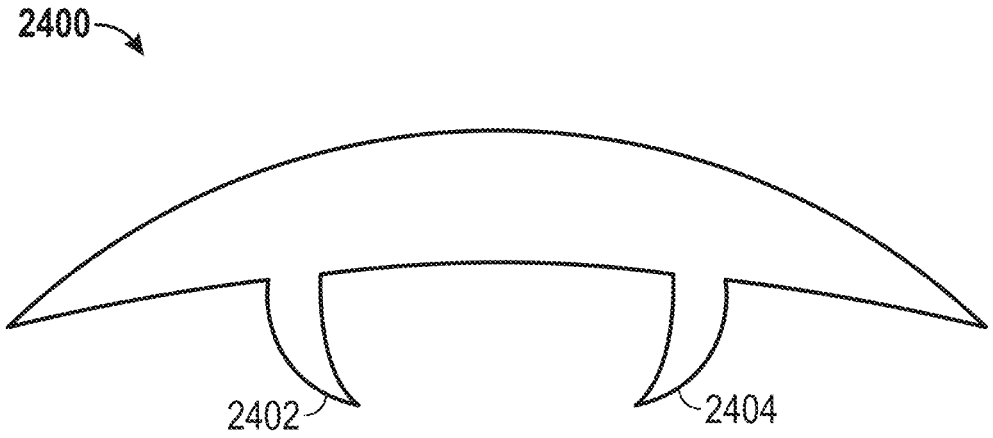


FIG. 24

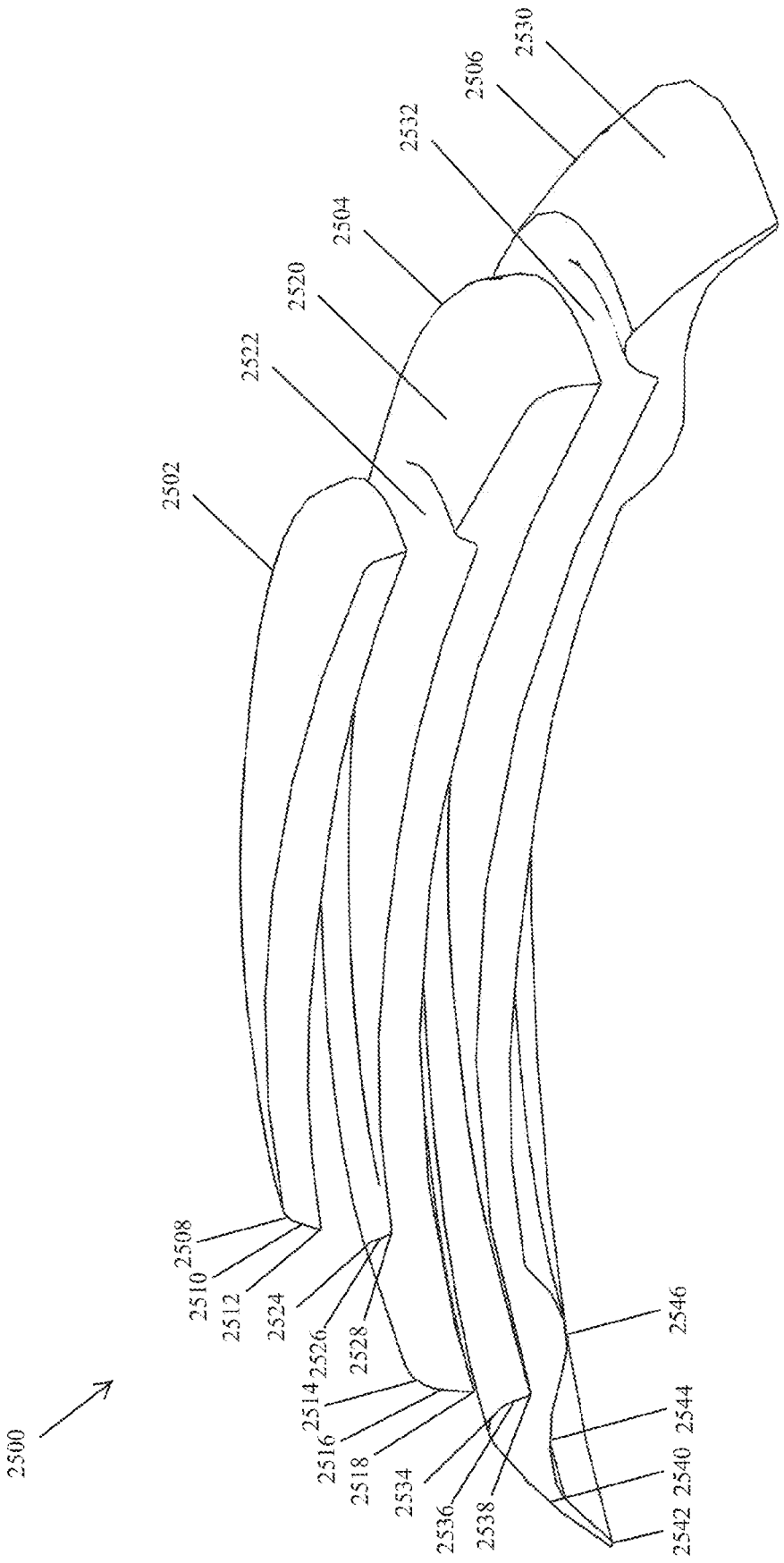
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FIG. 25

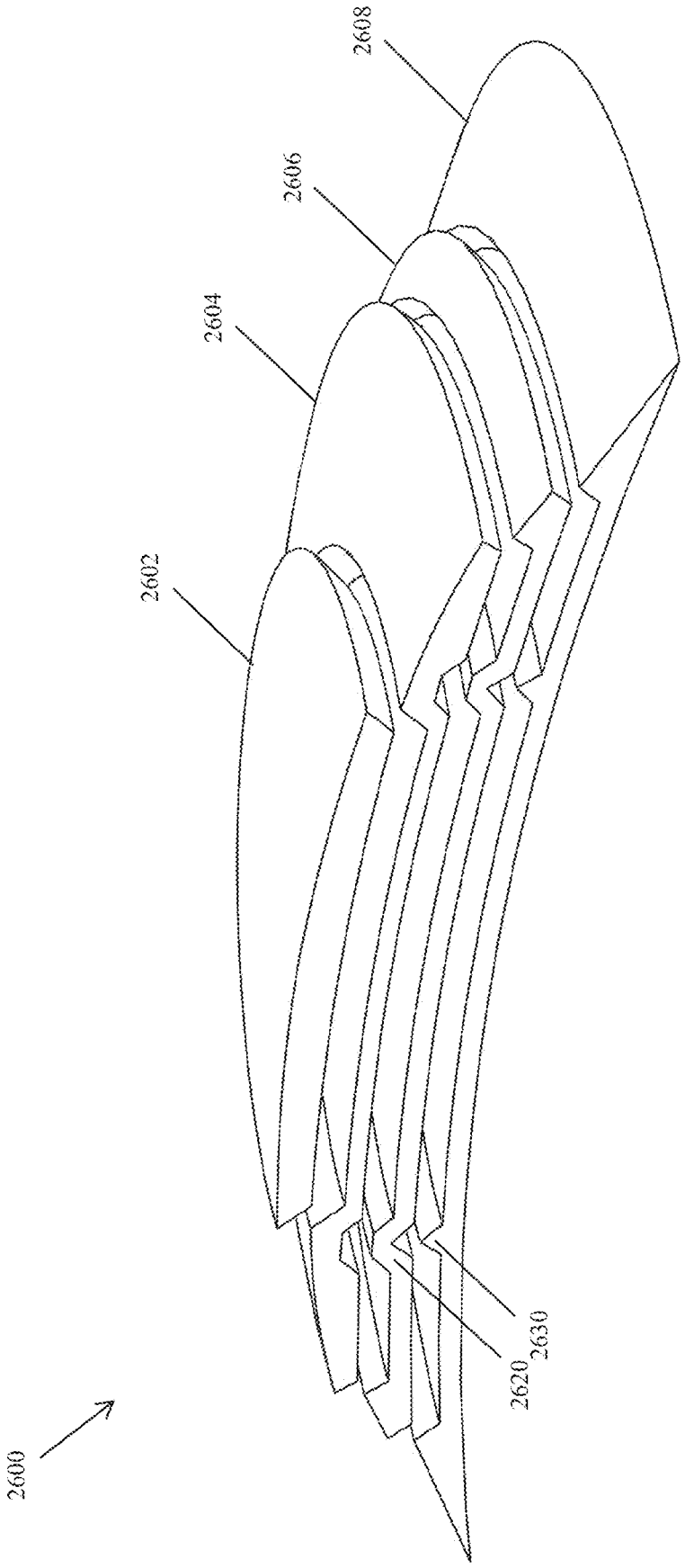


FIG. 26

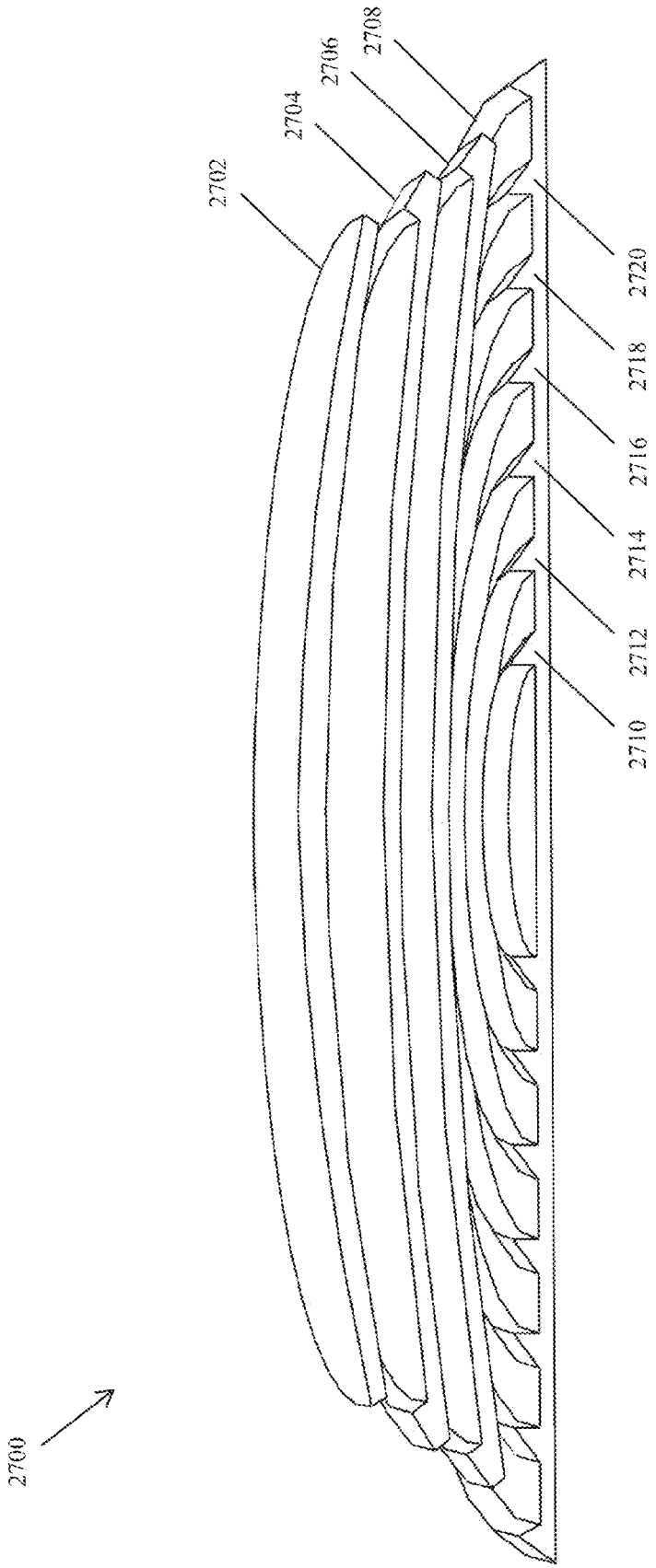


FIG. 27

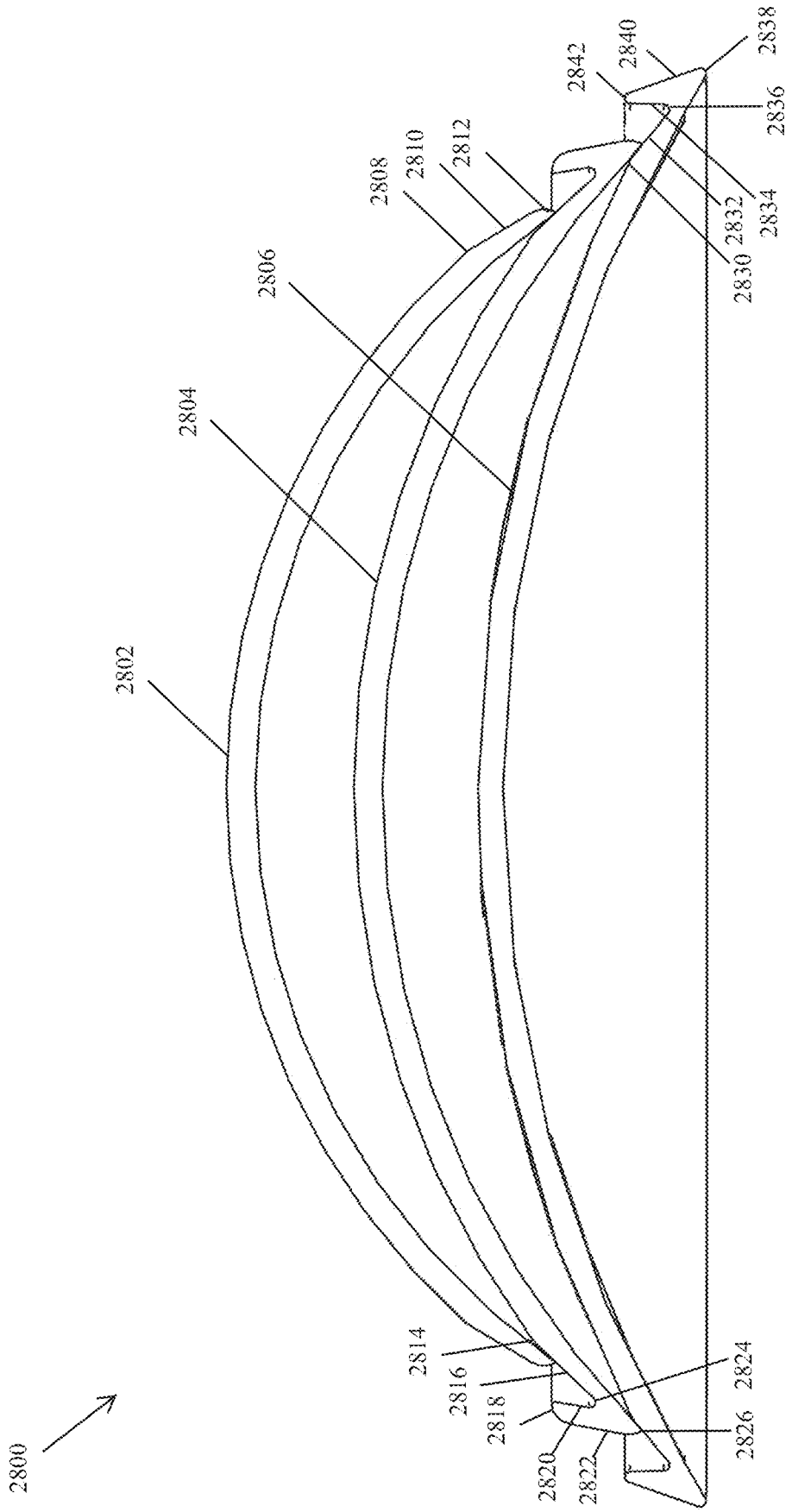
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FIG. 28

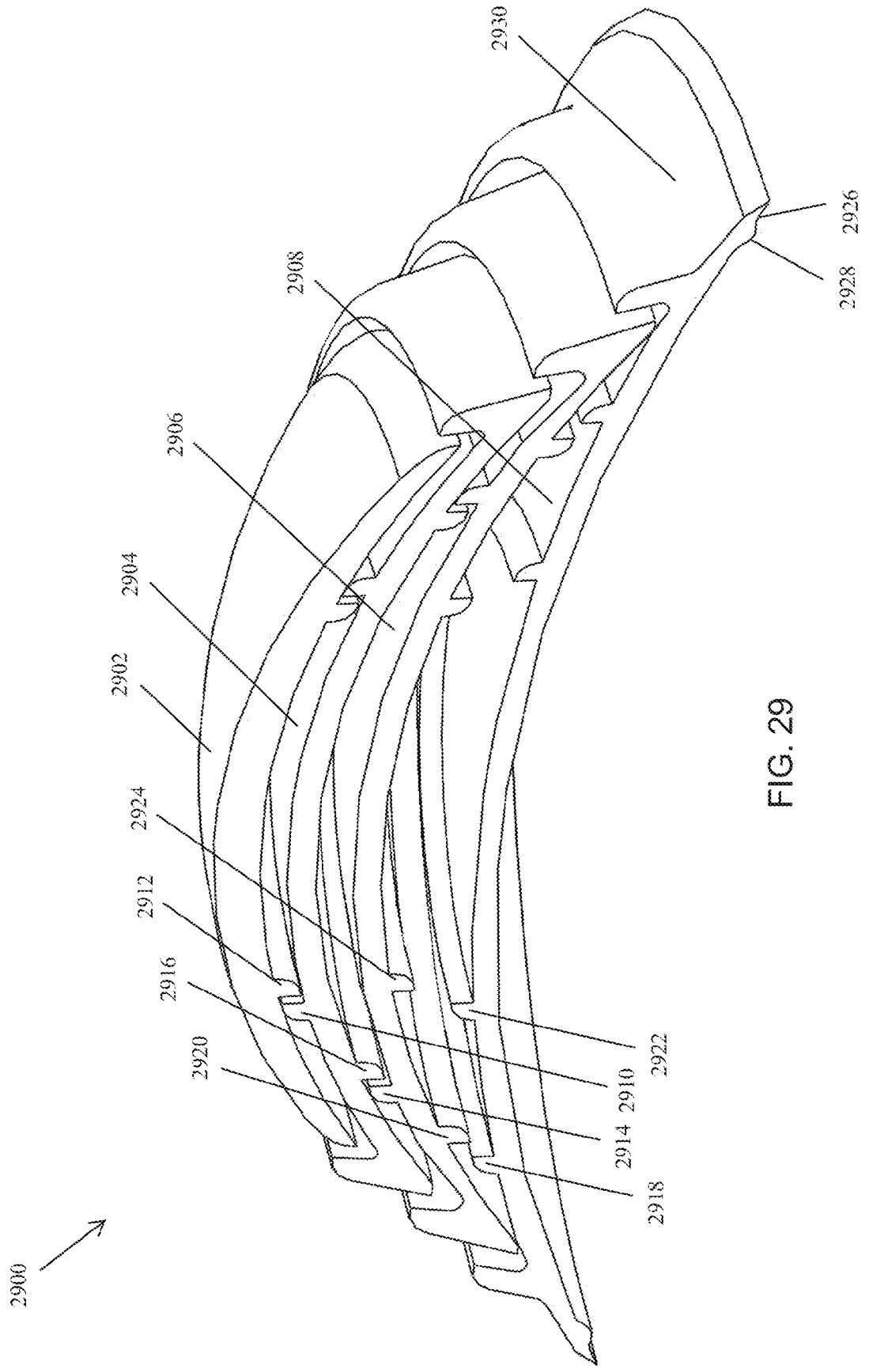
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FIG. 29

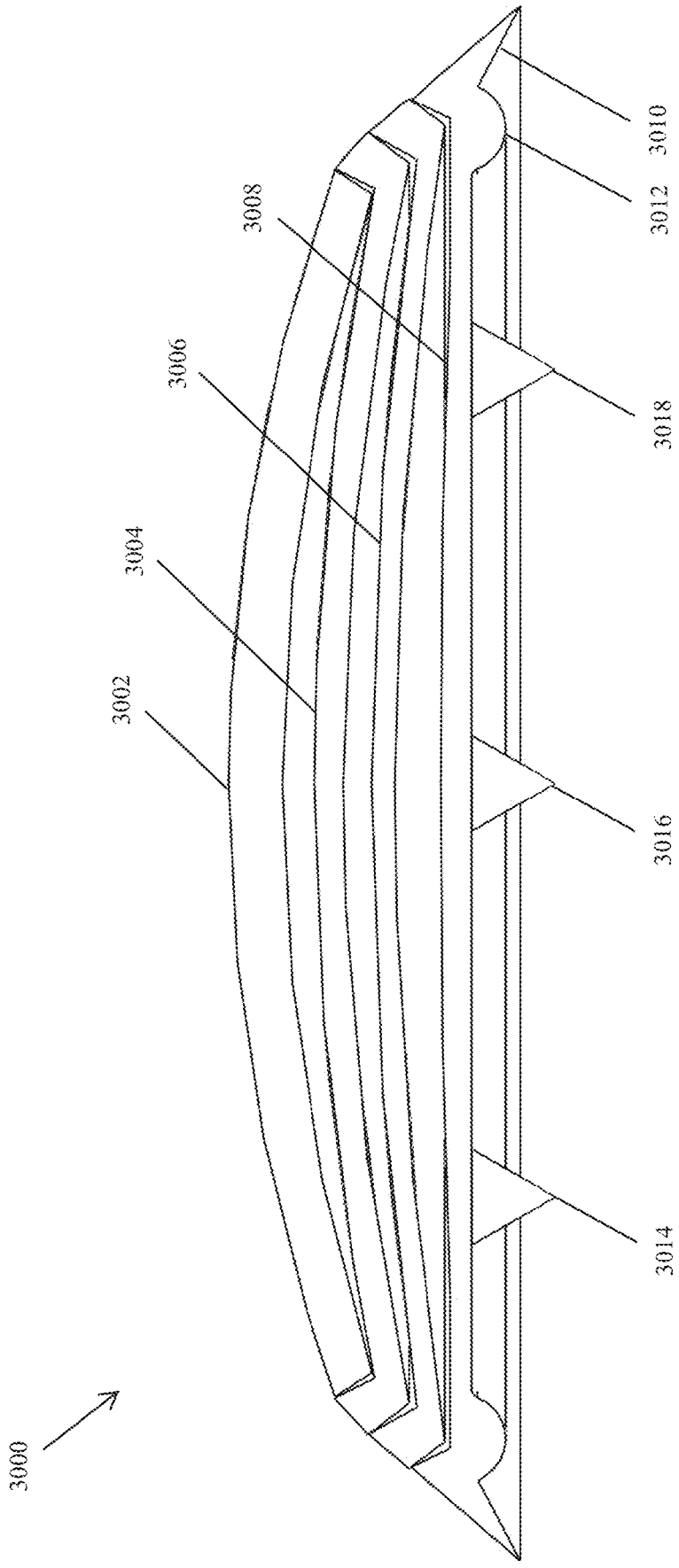


FIG. 30

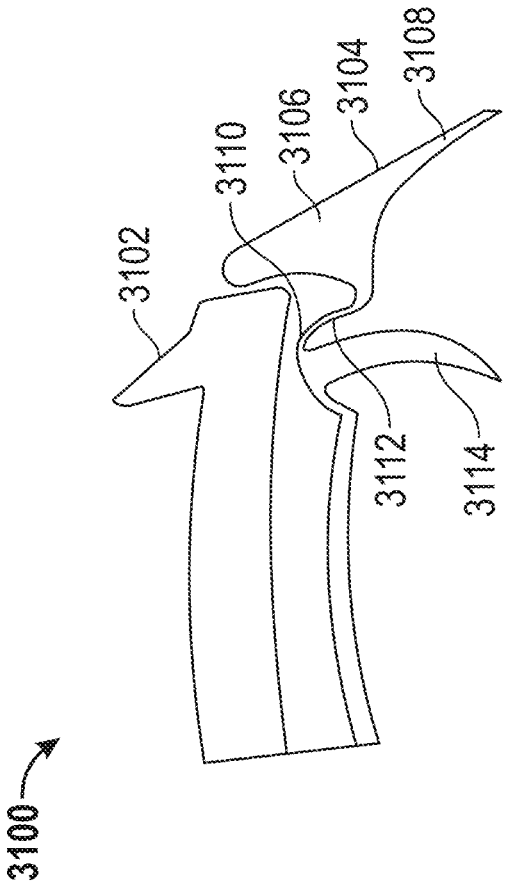


FIG. 31

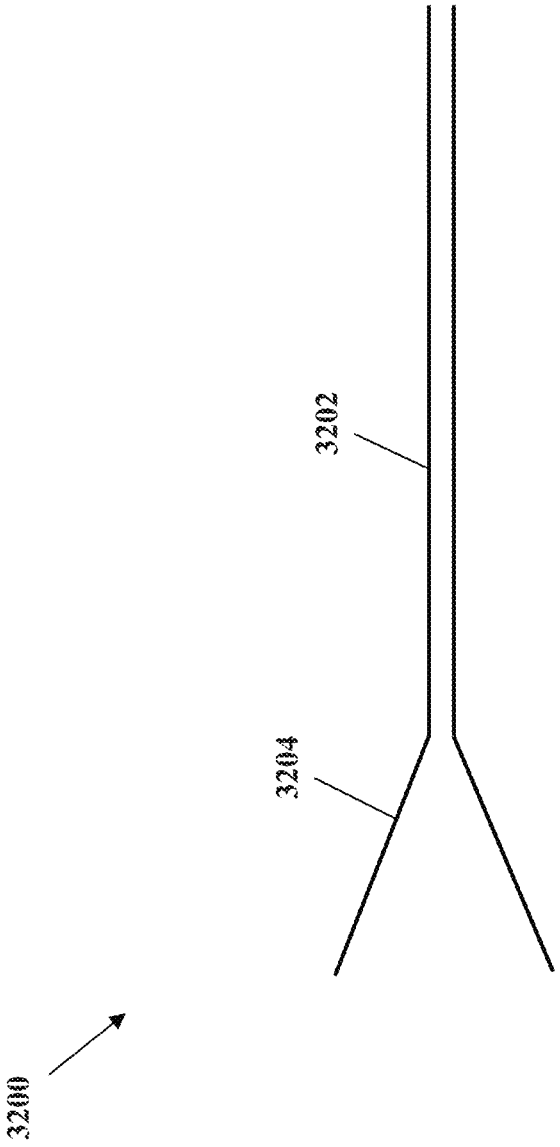


FIG. 32

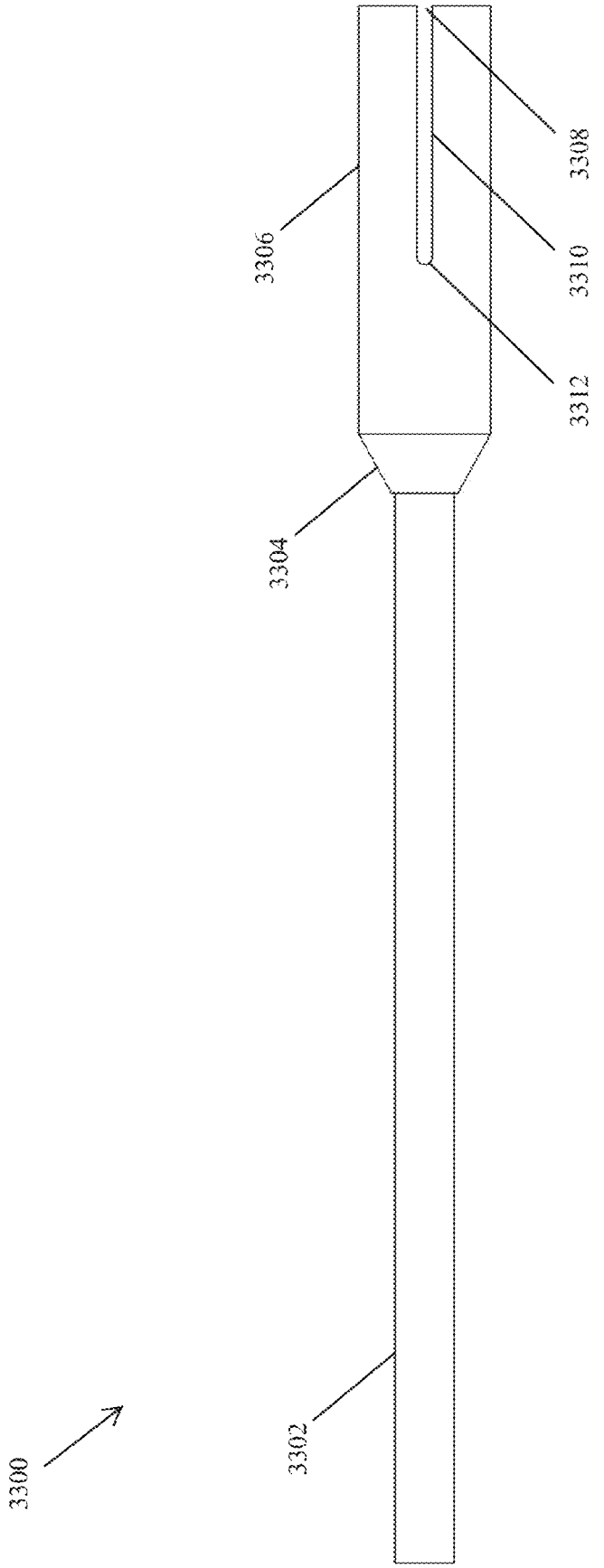


FIG. 33A

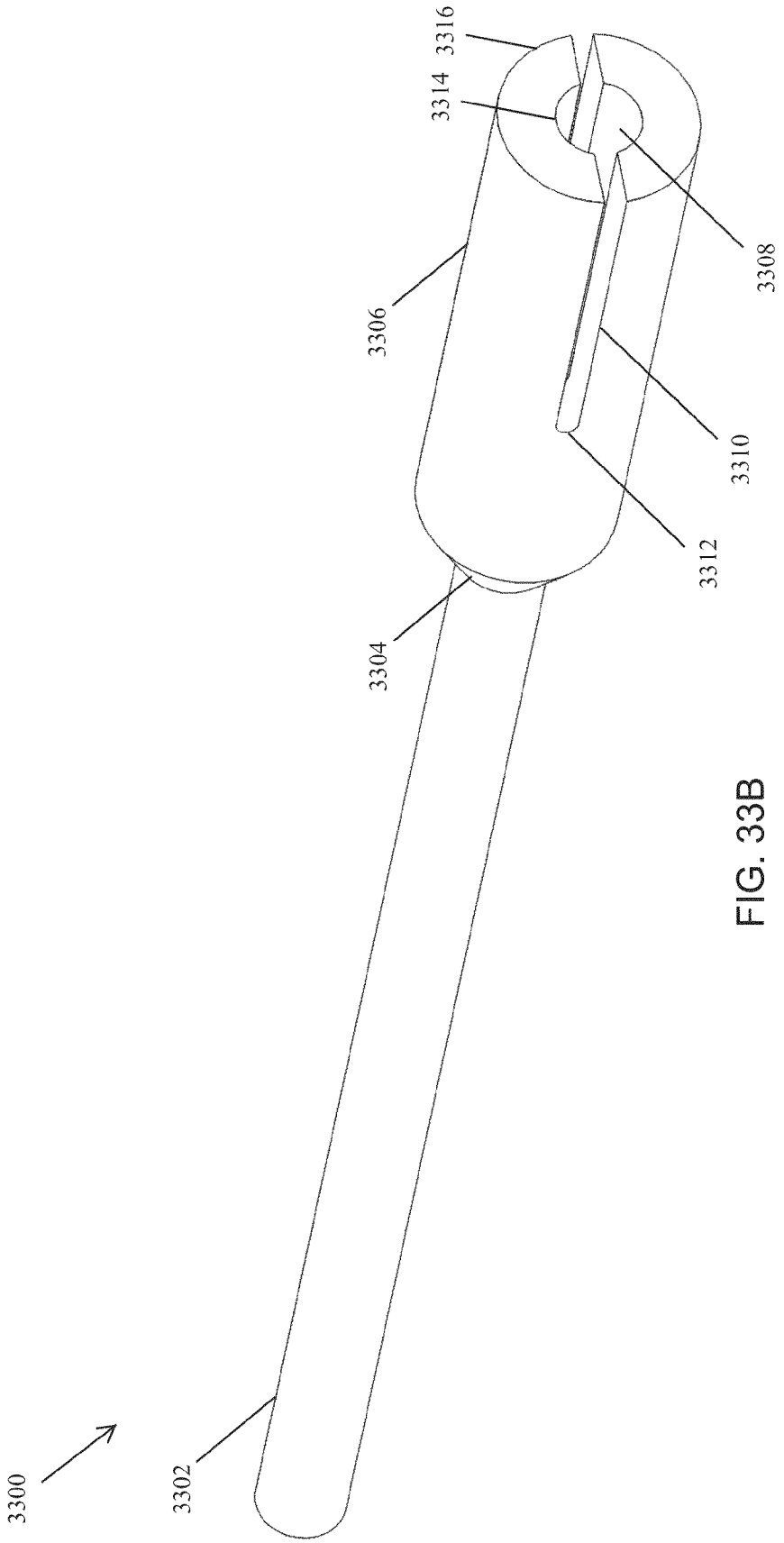


FIG. 33B

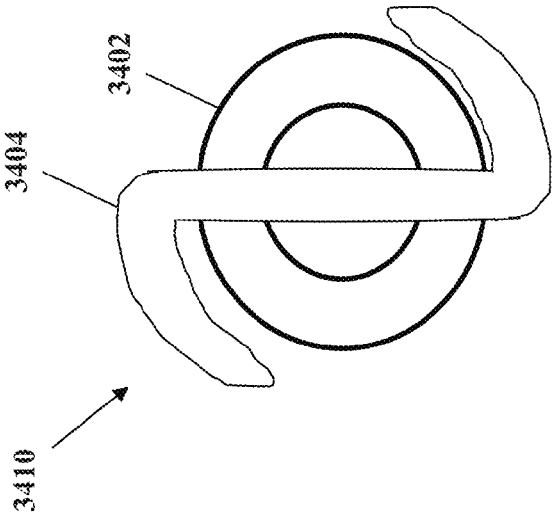


FIG. 34B

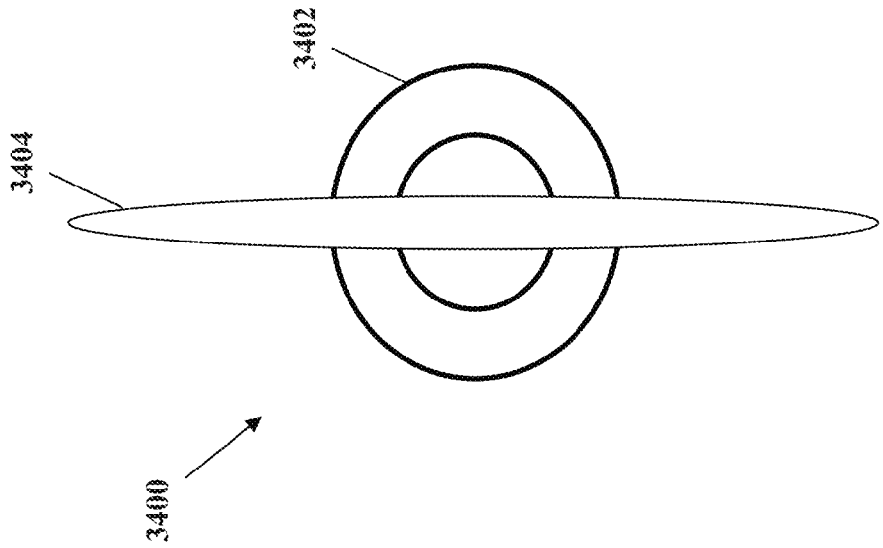


FIG. 34A

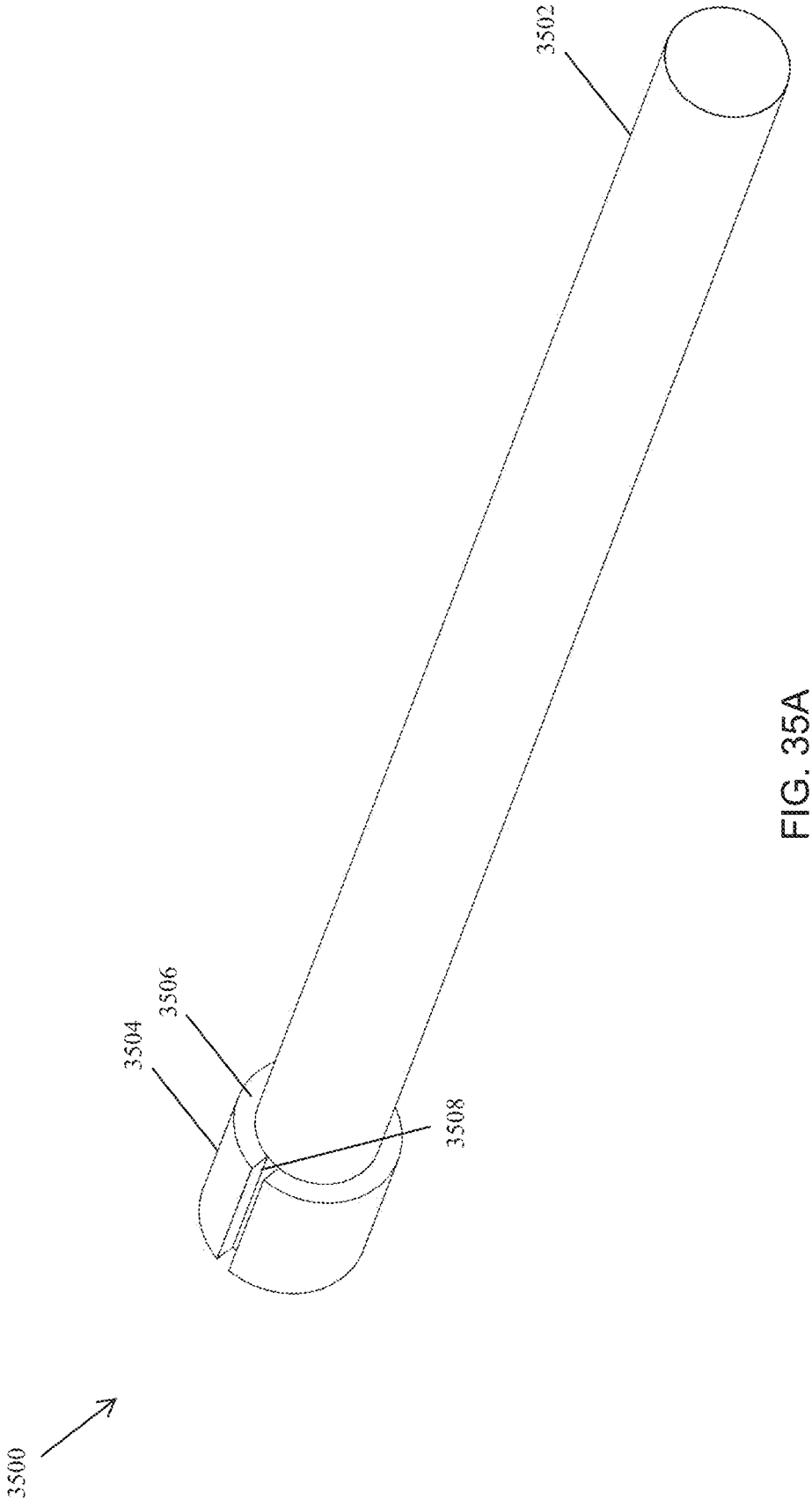


FIG. 35A

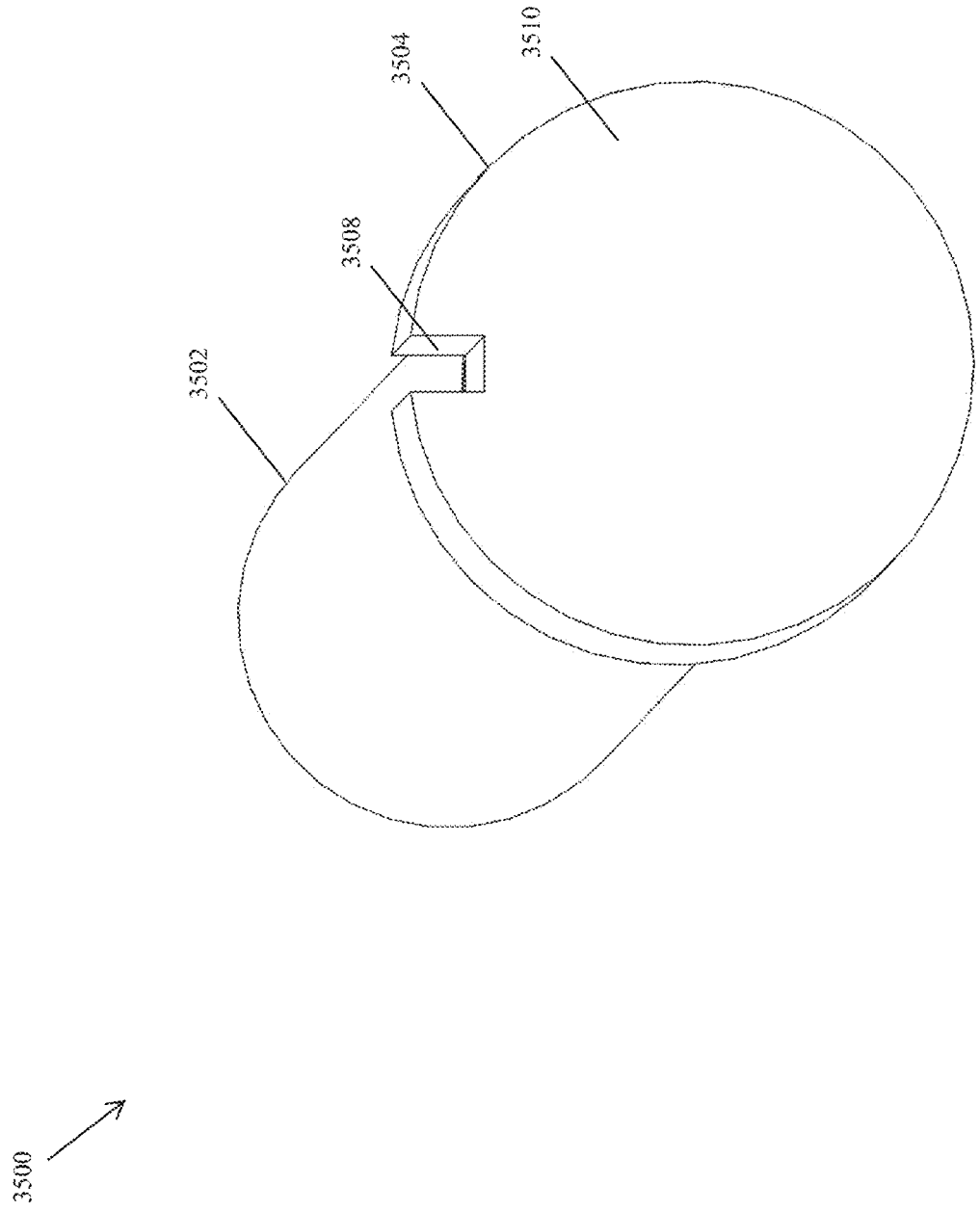


FIG. 35B

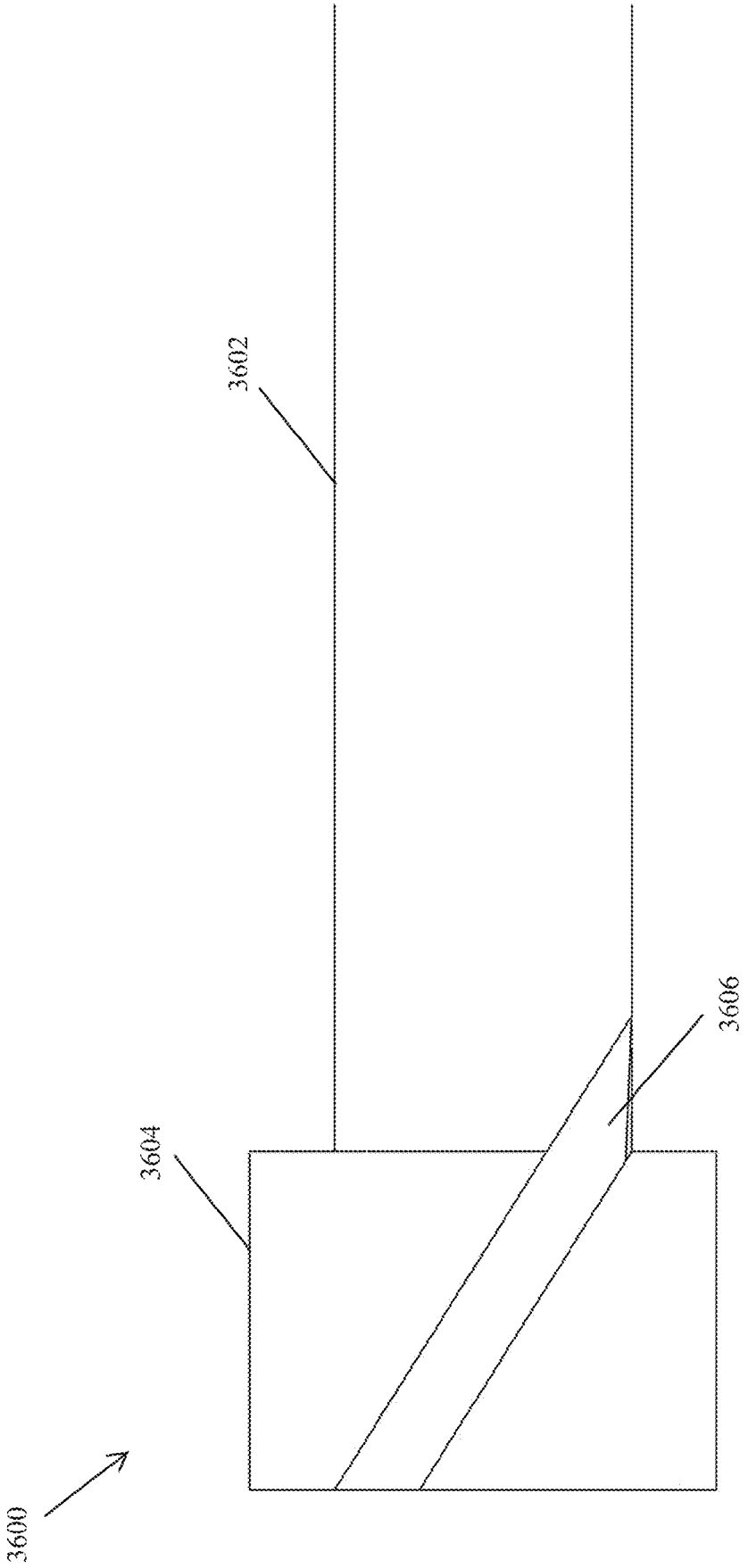


FIG. 36A

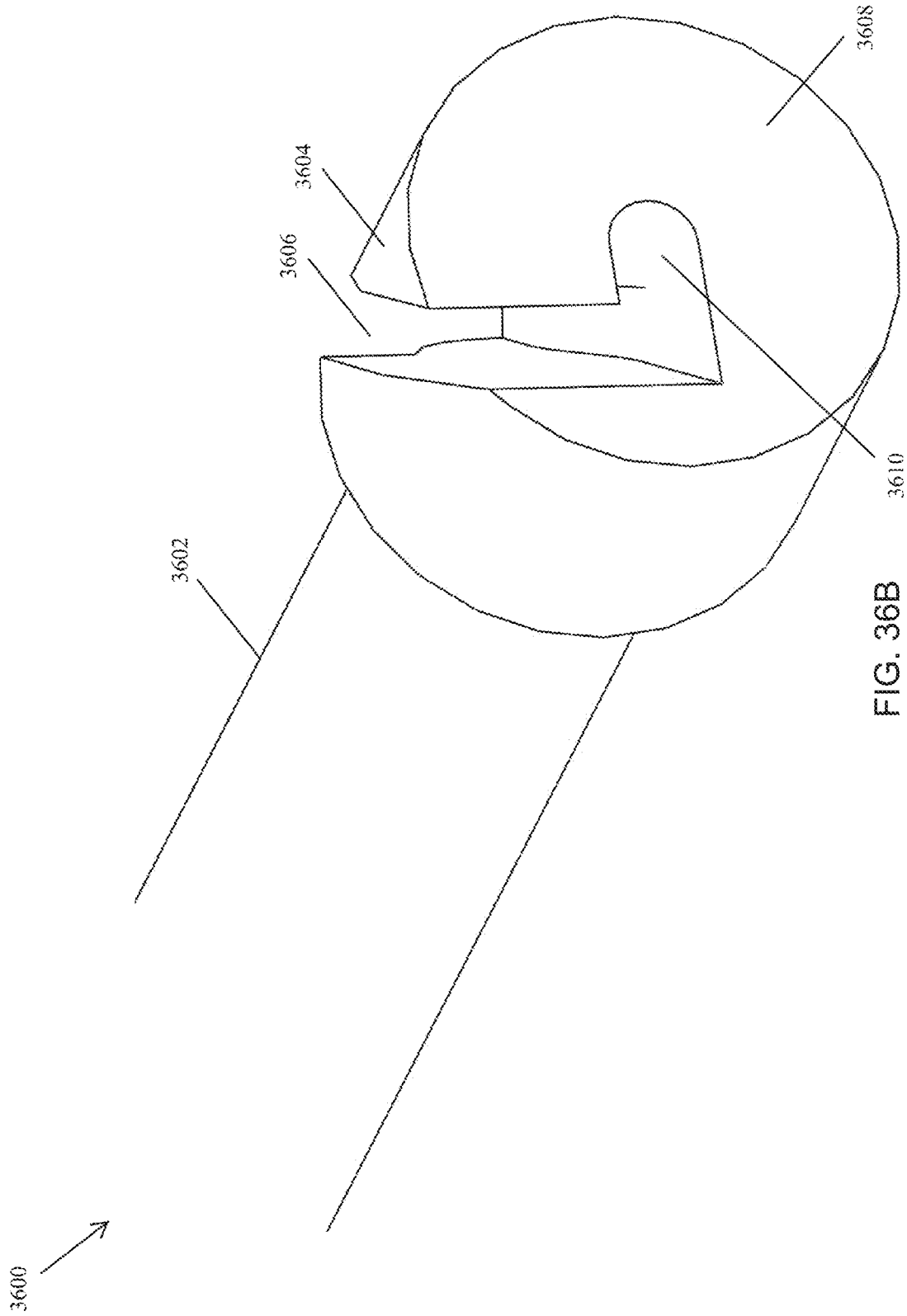


FIG. 36B

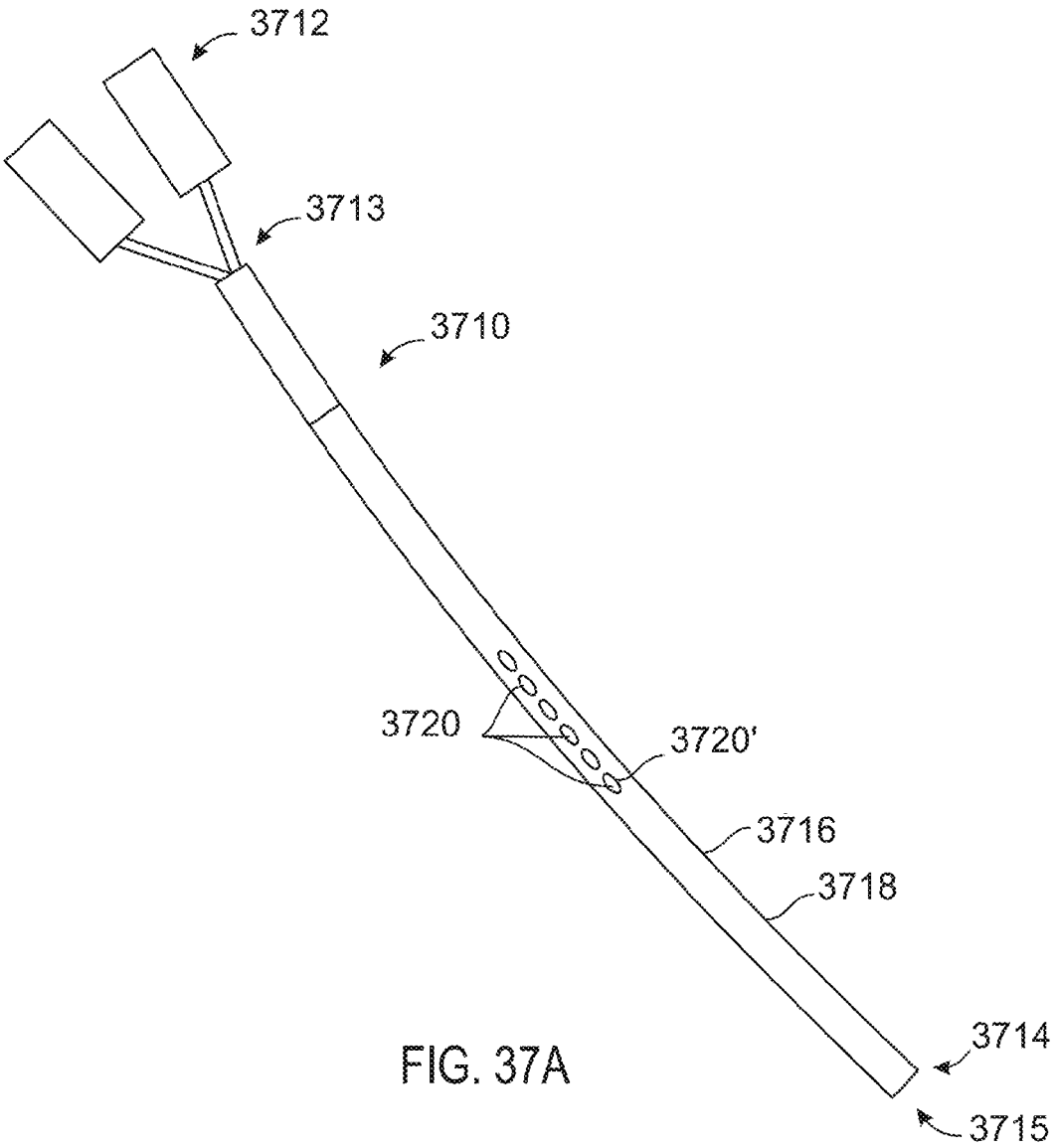


FIG. 37A

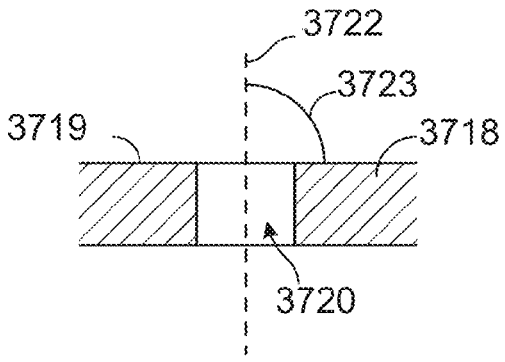


FIG. 37B

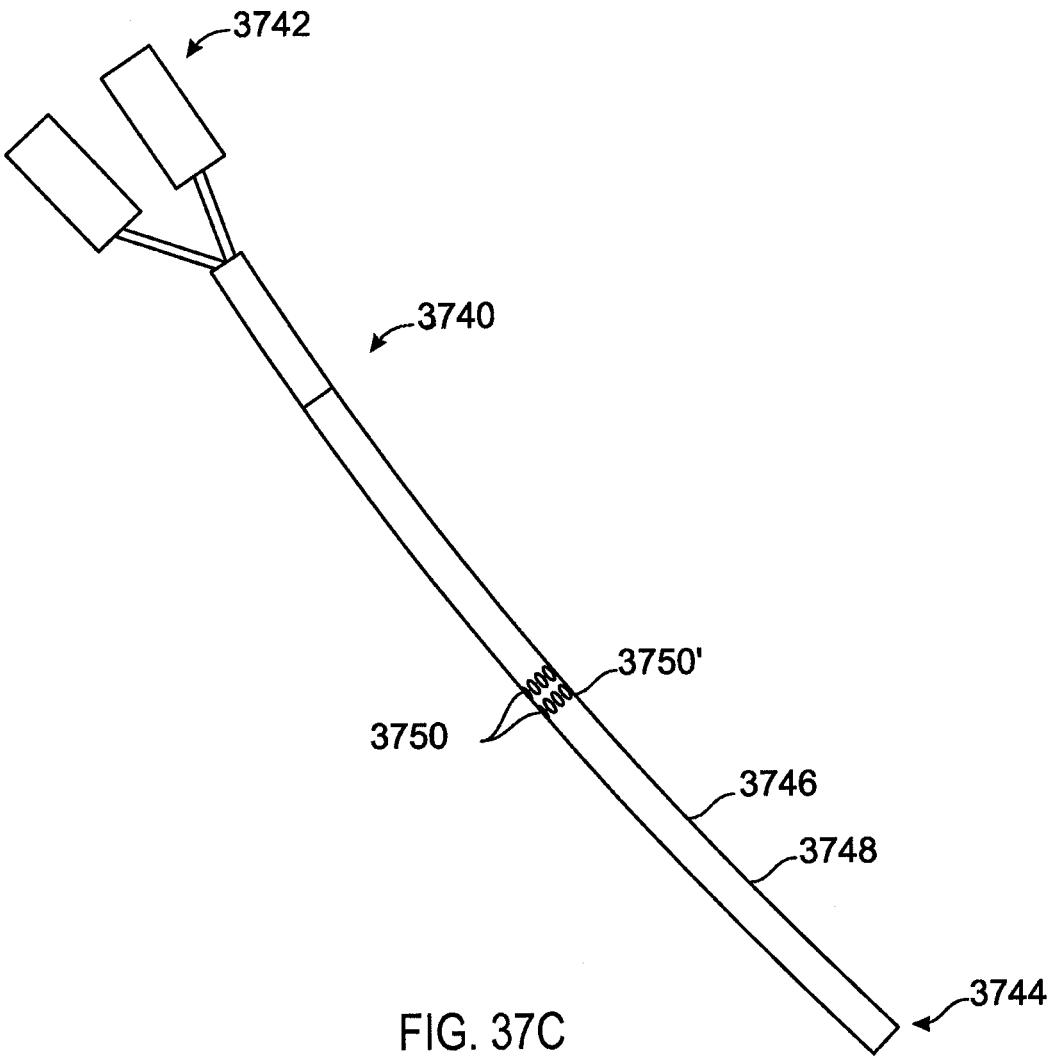


FIG. 37C

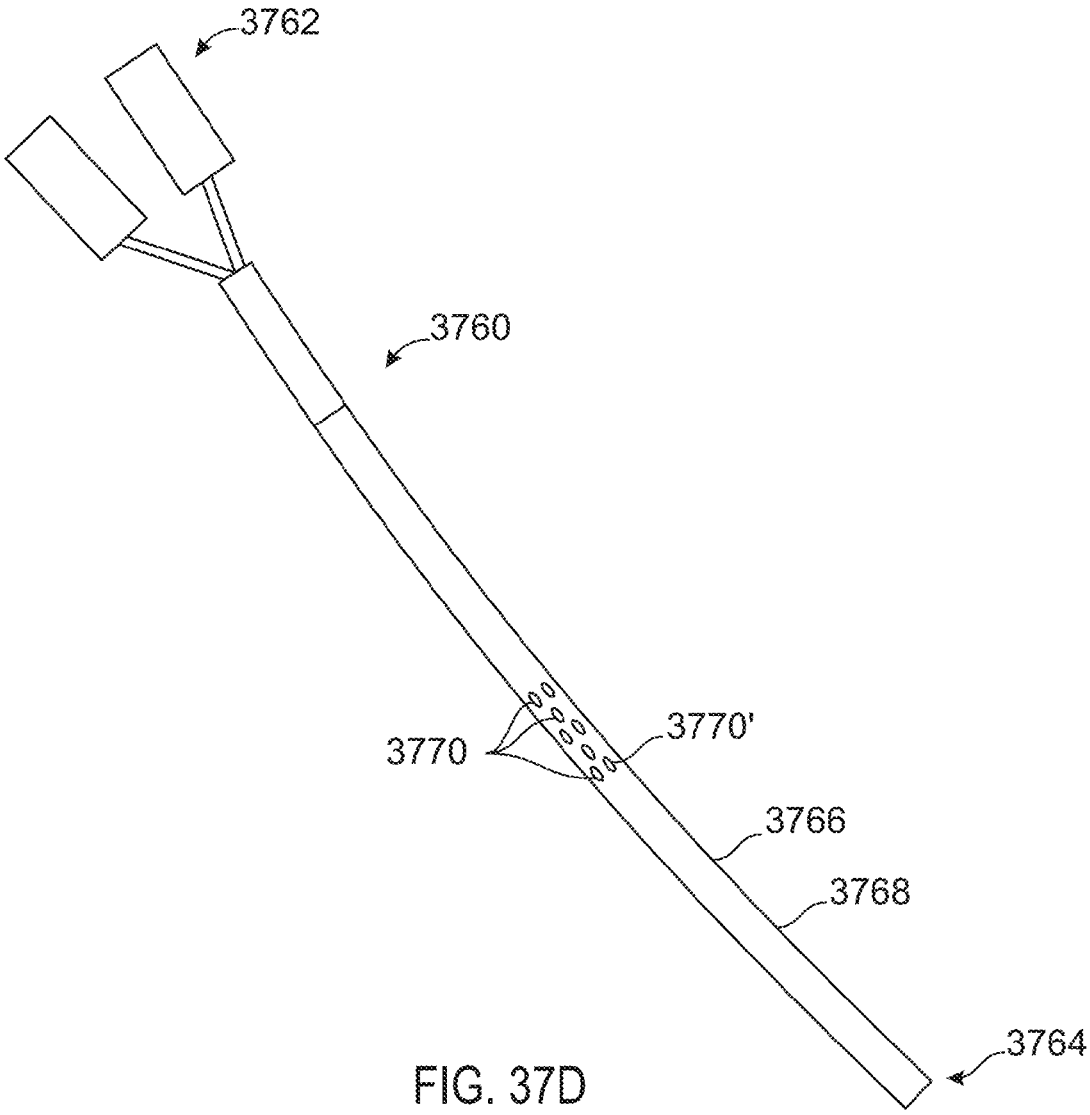


FIG. 37D

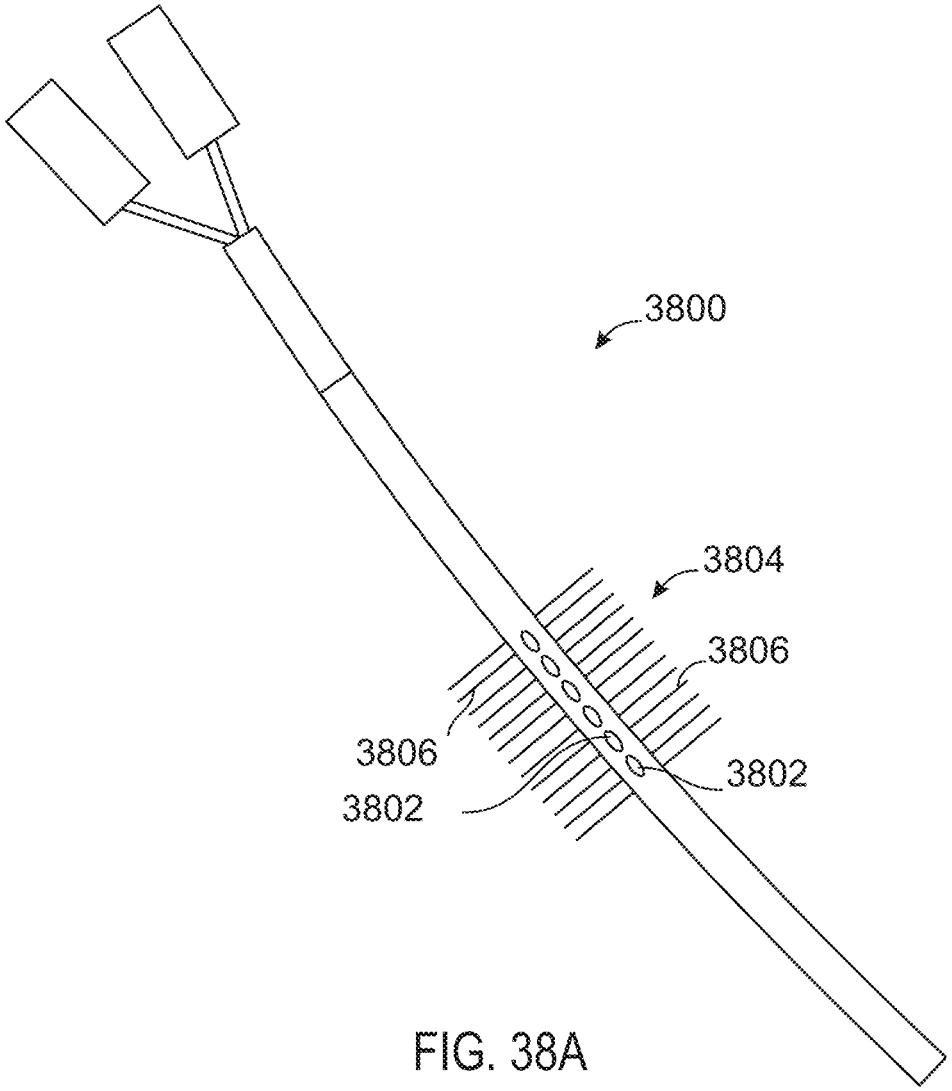


FIG. 38A

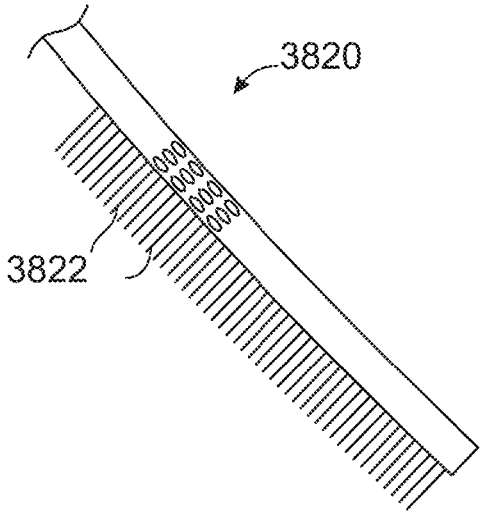


FIG. 38B

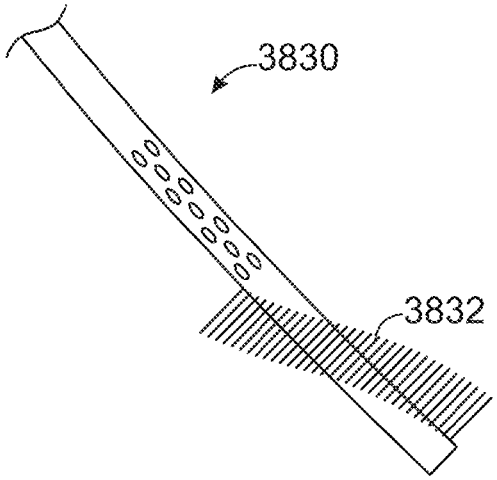


FIG. 38C

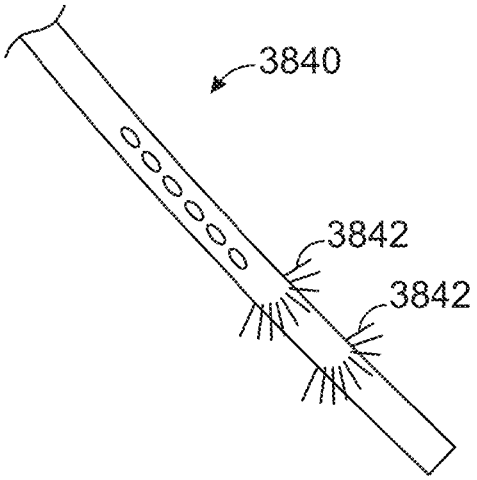


FIG. 38D

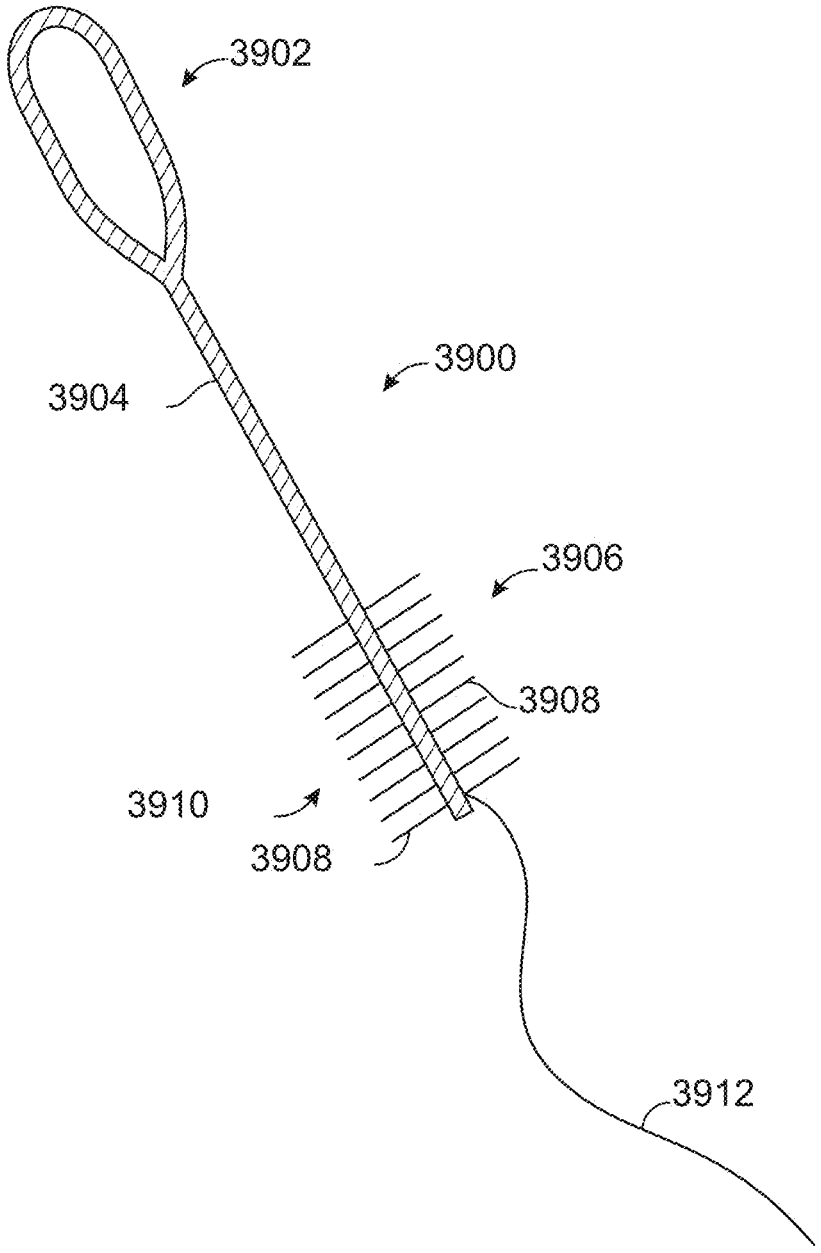


FIG. 39

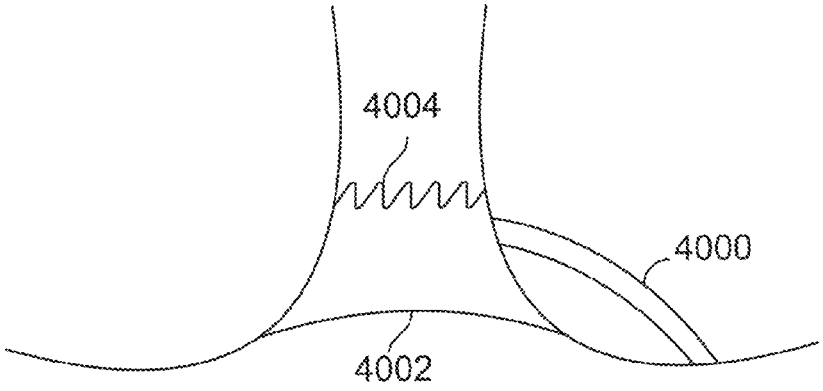


FIG. 40A

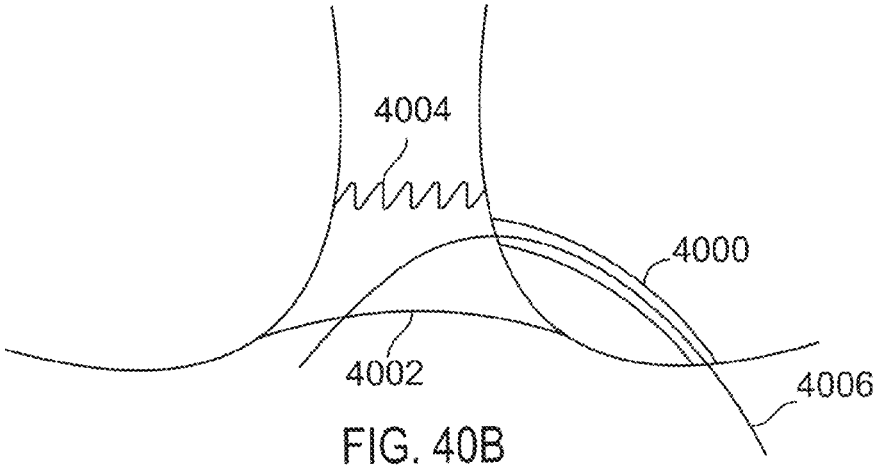


FIG. 40B

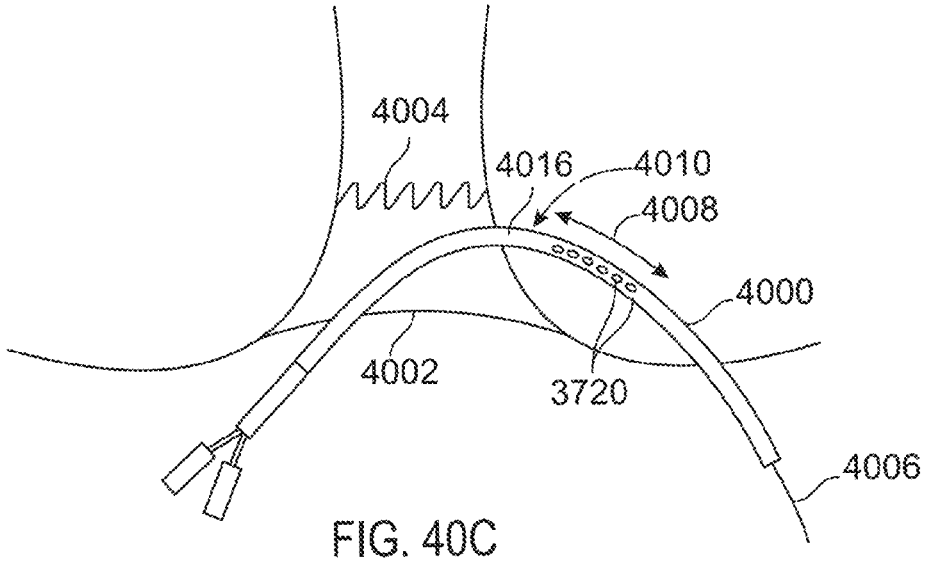


FIG. 40C

# FISTULA TREATMENT DEVICES AND RELATED METHODS

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119(e) to U.S. Provisional Ser. No. 61/497,899, filed Jun. 16, 2011, and U.S. Provisional Ser. No. 61/498,495, filed Jun. 17, 2011, which are hereby incorporated by reference in their entireties.

## TECHNICAL FIELD

The present invention relates to medical apparatus and methods. More specifically, the present invention relates to implantable devices for closing fistulas and methods of using such devices.

## BACKGROUND

Fistulas are a major cause of morbidity and mortality, as there are over one hundred thousand cases of pathologic fistulas a year, which account for over ten thousand deaths. They cost the healthcare system billions of dollars each year to treat.

Fistulas are tissue-lined connections between body cavities and hollow organs or between such cavities or organs and the surface of the body. The fistula tract includes a void or potential void in the soft tissues extending from a primary fistula opening to a blind ending or leading to one or more secondary fistula openings, sometimes following along tissue planes of organs or between organs. Fistulas frequently develop as a consequence of infections or accompany abscess formations. Although some fistulas are purposely created for therapeutic purposes such as tracheostomy tracts, gastric feeding tube tracts, or arteriovenous fistulas for dialysis access, pathological fistulas are abnormal tracts that typically occur either congenitally or form after surgery, surgery-related complications, or trauma. They are most often open tracts that have epithelialized, endothelialized, or mucosalized.

Fistulas can form between almost any two-organ systems, or multiple organs between different sites of the same organ. For example, they may occur between internal organs and skin (enterocutaneous fistulas, gastrocutaneous fistulas, anal fistulas, rectovaginal fistulas, colocutaneous fistulas, vesicolocutaneous fistulas, intestinocutaneous fistulas, tracheocutaneous fistulas, bronchocutaneous fistulas, etc.) or between internal organs themselves (tracheal-esophageal fistulas, gastrointestinal fistulas, colovesicular fistulas, palatal fistulas, etc.). Fistulas may also form between blood vessels such as arteriovenous fistulas.

Although fistulas may form in many locations in the body, they are almost universally highly morbid to patients and difficult for clinicians to treat. For example, enterocutaneous fistulas are one of the most feared complications of abdominal surgery. Enterocutaneous fistulas are abnormal connections that form between the bowel and skin and can occur after abdominal surgery, after trauma, or as a complication of Crohn's disease. Some reports estimate that enterocutaneous fistulas may form in as many as 1% of patients that undergo major abdominal surgery. They often require months of supportive care and/or major abdominal surgery. The overall mortality rate for patients that develop enterocutaneous fistulas remains high at around 20%.

Current options for treatment of enterocutaneous fistulas include long-term conservative management or major surgery. In a first option, the patients are placed on restricted enteric intake and managed with parenteral nutritional support. The fistula leakage is controlled using a stoma bag. If the fistula output is high, drains are sometimes placed to try and control the fistula output. Spontaneous closure is relatively low at around 25%. If fistulas fail to spontaneously close with current management after 5 weeks of bowel rest, then many surgeons advocate surgical treatment at this point, though supportive care could continue indefinitely. Patients with open fistula tracts often have ongoing associated malnutrition and electrolyte imbalance issues as well as chronic non-healing abdominal wounds.

A second option is a major surgery, which has a mortality rate near 30%. The surgery involves resection of the diseased intestinal segment, extirpation of the fistula, and debridement of the fistulous tract through the abdominal wall and subcutaneous tissue. This major abdominal surgery often requires blood transfusion and post-operative ICU admissions. As a result of chronic inflammation and having abdomens that have been previously operated on, these patients typically form dense adhesions and have highly friable tissues. In addition, these patients can be severely malnourished. These conditions make operations on enterocutaneous fistulas extremely difficult and dangerous. After the surgery the patient is put on total parenteral nutrition ("TPN") for several more days before the patient can be weaned off TPN and slowly introduced to normal foods.

Other treatment options may include implantable devices designed to aid in the closure of the fistula. These devices, however, may cause adverse immunological reactions in patients, may allow leakage of fluid around them, or may migrate or become dislodged when the patient exerts himself, such as during exercise. There is a need in the art for an implantable device for closing a fistula that reduces the chance of adverse immunological reactions, and the leakage of fluid through the fistula tract, and that has a reduced chance of migration or dislodgement during use.

## SUMMARY

Disclosed herein are implantable fistula closure devices and related kits and methods. In some embodiments, a distal anchor for an implantable fistula treatment device may comprise a suture, and a plurality of foldable members including at least a distal-most foldable member and a proximal-most foldable member, wherein the distal-most foldable member comprises a suture attachment structure, wherein the proximal-most foldable member is configured to couple to a surface of a body lumen at a distal opening of a fistula, wherein the proximal-most foldable member is configured to occlude the fistula at the distal opening, wherein the proximal-most foldable member is configured to slide along the suture attached to the suture attachment structure, wherein the proximal-most foldable member comprises a proximal first average dimension substantially parallel to a longitudinal axis of the suture, a proximal second average dimension orthogonal to the proximal first average dimension, and a proximal third average dimension orthogonal to the proximal first and second average dimensions, the proximal first average dimension being no greater than 10% of the greater of the proximal second and third average dimensions, and wherein the distal-most foldable member comprises a distal first average dimension substantially parallel to the longitudinal axis of the suture, a distal second average dimension orthogonal to the distal first average dimension, and a distal third average dimension orthogonal to the distal first and second average dimensions, the distal first average dimension being no greater than 30% of the greater of the distal second and third

average dimensions. The distal anchor may comprise at least one additional foldable member positioned between the distal-most foldable member and the proximal-most foldable member. The proximal second average dimension of the proximal-most foldable member of the distal anchor may be larger than the distal second average dimension of the distal-most foldable member. The distal second average dimension of the distal-most foldable member of the distal anchor may have less than or equal to 20% of the proximal second average dimension of the proximal-most foldable member.

The proximal-most foldable member of the distal anchor may comprise a generally circular perimeter. The proximal-most foldable member of the distal anchor may comprise a generally concave shape. The distal-most foldable member of the distal anchor may comprise a generally concave shape, and a radius of curvature of the distal-most foldable member may be smaller than a radius of curvature of the proximal-most member.

The distal anchor may comprise coupling members on opposing surfaces of at least two of the plurality of foldable members. The coupling members of the distal anchor may comprise complementary protrusions or recesses on the surfaces of the members. The complementary protrusions of the distal anchor may comprise teeth. The coupling member of at least one foldable member of the distal anchor may comprise a curing agent. The coupling member of the at least one foldable member of the distal anchor may comprise a capsule enclosing the curing agent. The capsules of the distal anchor may be configured to rupture upon contact with another foldable member. The coupling members of at least two foldable members of the foldable members may be configured to produce attracting electromagnetic forces.

Each of the foldable members may decrease in flexibility from the proximal-most to the distal-most foldable member. The proximal first average dimension of the proximal-most foldable member may be less than the distal first average dimension of the distal-most foldable member. A density of the proximal-most foldable member of the distal anchor may be less than a density of the distal-most foldable member.

A proximal surface of the proximal-most foldable member of the distal anchor may comprise a grapple configured to attach the proximal-most foldable member to a surface of the body lumen. A distal surface of the proximal-most foldable member of the distal anchor may comprise a grapple activation structure configured to activate the grapple upon contact with the proximal surface of another foldable member. The grapple activation structure of the distal anchor may comprises a protrusion.

At least one of the plurality of foldable members of the distal anchor may include a protrusion configured to resist relative movement between at least two of the plurality of foldable members. At least one other of the plurality of foldable members of the distal anchor may include a recess configured to receive the protrusion. At least one of the plurality of foldable members of the distal anchor may comprise at least two protrusions configured to resist relative movement between the at least two of the plurality of foldable members.

The distal-most foldable member of the distal anchor may be pre-attached to the suture at the suture attachment mechanism. The proximal-most foldable member may not be pre-attached to the suture.

In some embodiments, a method of sealing a fistula tract may comprise positioning a first sealing member adjacent a distal opening of a fistula tract at a location outside of the fistula tract and positioning a second sealing member against the first sealing member at a location outside of the fistula tract, wherein at least one dimension of the second sealing member is larger than the first sealing member. The method of sealing a fistula tract may also comprise passing the first sealing member through the fistula tract before positioning the first sealing member at the location outside of the fistula tract. Positioning a second sealing member in the method of sealing a fistula tract may comprise positioning an interfit structure of the second sealing member against a complementary interfit structure of the first sealing member. The method of sealing a fistula tract may comprise positioning a third sealing member against the second sealing member at a location outside of the fistula tract, wherein at least one dimension of the third sealing member is larger than the second sealing member. The method of sealing a fistula tract may comprise positioning a porous body within the fistula tract after positioning the second sealing member against the first sealing member. The method of sealing a fistula tract may comprise tensioning a tether member attached to the first sealing member to deform an aggregate distal anchor comprising the first and second sealing members toward the distal fistula tract. The method of sealing a fistula tract may comprise sealing the aggregate distal anchor at an outer edge seal and an inner seal that is spaced apart from the outer edge seal. The method of sealing a fistula tract may comprise securing the tether to maintain the tensioning of the tether member. Securing the tether in the method of sealing a fistula tract may comprise securing the tether to a resilient structure.

In some embodiments, a fistula irrigation catheter may comprise a tubular member, where the tubular member may comprise a proximal end, a distal end and a wall portion therebetween, the wall portion having a plurality of apertures therethrough, wherein the distalmost aperture of the plurality of apertures is located at least about 2 centimeters from the distal end of the tubular member, and wherein the plurality of apertures are oriented to provide non-orthogonal irrigation therethrough. The plurality of apertures of the fistula irrigation catheter may be configured to provide bidirectional irrigation. The fistula irrigation catheter may also comprise a brushing member configured to brush a fistula tract.

In some embodiments, a method of irrigating a fistula tract comprises inserting an irrigation catheter into the fistula tract, grasping both a proximal end of the irrigation catheter and a distal end of the irrigation catheter, and moving the irrigation catheter proximally and distally within the fistula tract to irrigate different portions of the fistula tract. The irrigation catheter of the method of irrigating a fistula tract may comprise a brushing member, and the method may comprise brushing the fistula tract.

While multiple embodiments are disclosed, still other embodiments fistula treatment devices, kits and methods will become apparent to those skilled in the art from the following Detailed Description. As will be realized, the devices, kits and methods are capable of modifications in various aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is an isometric view of an embodiment of an implantable fistula closure device having a segmented body and located in a fistula tract in a compressed or non-expanded state.

FIG. **1**B is the same view as FIG. **1**A, except the implantable fistula closure device is in a non-compressed or expanded state within the fistula tract.

FIG. **1**C is an isometric view of the implantable fistula closure device located in a fistula tract in a compressed or

non-expanded state, where the distal most body of the device body has a conical shape, as opposed to a cylindrical shape.

FIG. **1**D is the same view as FIG. **1**C, except the implantable fistula closure device is in a non-compressed or expanded state within the fistula tract.

FIGS. **2**A-**2**D provide an illustrative depiction of an embodiment of a method of sealing a fistula tract using a fistula treatment device; FIG. **2**E depicts an embodiment of a dressing being used with the fistula treatment device of FIGS. **2**A-**2**D after the fistula tract has been sealed; FIG. **2**F depicts an embodiment of a seal or cover being used with the fistula treatment device of FIGS. **2**A-**2**D after the fistula tract has been sealed.

FIGS. **3**A and **3**B illustrate the sealing of an embodiment of an expandable member of a fistula treatment device.

FIG. **4** illustrates the actuation of an embodiment of a fistula treatment device to seal the expandable member shown in FIGS. **3**A and **3**B.

FIGS. **5**A-**5**C depict the sealing of an embodiment of an expandable member of a fistula treatment device.

FIG. **6**A is a perspective view of an embodiment of a proximal anchor of a fistula treatment device; FIG. **6**B is a side elevational view of the proximal anchor of FIG. **6**A; FIG. **6**C is a top view of the proximal anchor of FIG. **6**A.

FIGS. **7**A and **7**B provide an illustrative depiction of a method of using an embodiment of a proximal anchor of a fistula treatment device.

FIG. **8** shows an embodiment of a fistula treatment kit.

FIG. **9**A is a side view of an embodiment of a delivery device for an implantable fistula closure device, where a portion of the delivery device is inserted into a fistula tract.

FIG. **9**B is the same view as FIG. **9**A, except the entire delivery device is shown inserted into the fistula tract.

FIG. **9**C is the same view as FIG. **9**A, except the delivery device is withdrawn from about the device body and the device body is fully expanded.

FIGS. **10**A-**10**F are isometric views of a fistula closure device illustrating one embodiment of a method of treating a fistula.

FIG. **11** is a perspective illustration of an embodiment of a component of a fistula treatment device.

FIG. **12** is a perspective illustration of an embodiment of another component of a fistula treatment device.

FIG. **13**A is a superior view of an embodiment of a fistula closure device comprising a resilient annular collapsible distal end; FIGS. **13**B and **13**C are inferior and side elevational views of the device in FIG. **13**A.

FIG. **14** is a schematic representation of the device in FIGS. **13**A-**13**C used with a proximal retaining structure and a plurality of tethered, expandable members attached to the device.

FIG. **15**A is a superior view of the proximal retaining structure in FIG. **14**; FIG. **15**B is a schematic side elevational view of an embodiment of a delivery instrument for the device depicted in FIG. **14**; FIGS. **15**C and **15**D are examples of an expandable member actuator and delivery catheter, respectively.

FIGS. **16**A and **16**B depict an exemplary embodiment of a distal anchor comprising multiple discs in a separated and a collapsed configuration, respectively.

FIGS. **17**A and **17**B illustrate various embodiments of multi-disc anchor configurations.

FIG. **18** is a cross-sectional side elevational view of one example of a multi-disc anchor.

FIG. **19** is a cross-sectional side elevational view of another example of a multi-disc anchor.

FIGS. **20**A-**20**C depicts various configurations of interdisc interfaces in a multi-disc anchor.

FIG. **21** is a cross-sectional side elevational view of another example of a multi-disc anchor, without the distalmost portion.

FIG. **22** is a cross-sectional side elevational view of another example of a multi-disc anchor, without the distalmost portion.

FIGS. **23**A-**23**C depicts various configurations of interdisc interfaces in a multi-disc anchor.

FIG. **24** depicts a tissue-engaging feature of an exemplary anchor.

FIG. **25** is a cross-sectional perspective view of another example of a multi-disc anchor.

FIG. **26** is a cross-sectional perspective view of another example of a multi-disc anchor.

FIG. **27** is a cross-sectional perspective view of another example of a multi-disc anchor.

FIG. **28** is a cross-sectional elevational view of another example of a multi-disc anchor.

FIG. **29** is a cross-sectional perspective view of another example of a multi-disc anchor.

FIG. **30** is a cross-sectional elevational view of another example of a multi-disc anchor.

FIG. **31** is a schematic cross-sectional view of a tissue support structure of another example of a multi-disc anchor.

FIG. **32** is a schematic cross-sectional view of a loading device for a fistula treatment device.

FIGS. **33**A-**33**B are side elevational and superior perspective views, respectively, of a delivery device for a fistula treatment device.

FIGS. **34**A-**34**B are schematic illustrations of a fistula treatment device loaded into the delivery device in FIGS. **33**A-**33**B, in an initial and a collapsed configuration, respectively.

FIGS. **35**A-**35**B are a superior perspective general view and a superior perspective distal detailed view of an exemplary push device for a fistula treatment device.

FIGS. **36**A-**36**B are side elevational and superior perspective distal details views of another example of a push device for a fistula treatment device.

FIG. **37**A is an illustrative depiction of an embodiment of a fistula irrigation catheter.

FIG. **37**B is a cross-sectional view of a region of the fistula irrigation catheter of FIG. **37**A, where the region includes an aperture.

FIG. **37**C is an illustrative depiction of another embodiment of a fistula irrigation catheter.

FIG. **37**D is an illustrative depiction of an additional embodiment of a fistula irrigation catheter.

FIG. **38**A is an illustrative depiction of an embodiment of a fistula irrigation and brushing catheter.

FIG. **38**B is an illustrative depiction of a portion of another embodiment of a fistula irrigation and brushing catheter.

FIG. **38**C is an illustrative depiction of a portion of an additional embodiment of a fistula irrigation and brushing catheter.

FIG. **38**D is an illustrative depiction of a portion of a further embodiment of a fistula irrigation and brushing catheter.

FIG. **39** is an illustrative depiction of an embodiment of a fistula brushing device.

FIGS. **40**A-**40**C provide an illustrative depiction of an embodiment of a method of irrigating a fistula tract.

## DETAILED DESCRIPTION

Fistula tracts **10** can be nonlinear or curvilinear and contain cavities of varying sizes at different intervals within the tract. Fistulas may also comprise multiple interconnected passages.

An implantable fistula closure device **5** disclosed herein employs advantageous design, configuration techniques and attributes to accommodate such constraints.

For example, and referring to FIGS. **1**A-**1**D, in some embodiments, the device **5** may have a segmented expandable body **13** formed of a plurality of individual expandable bodies or members **15** that are coupled together. The members **15** may be coupled together in an immediately adjacent abutting fashion or in a spaced-apart fashion (as shown). Upon insertion of the device **5** into the fistula tract **10** with the expandable members **15** in a collapsed or compressed state, the expandable members **15** are allowed to expand to fill the portion of the fistula tract **10** in which each expandable member **15** is located. It should be noted that the collapsed or compressed state allows for convenient insertion of the device **5** into the fistula tract **10**. Additionally, the segmented nature of the body **13** of the device **5** or, more specifically, the fact that the device's body **13** is formed of a plurality of individual members **15**, allows the body **13** to be more easily placed in, and to more readily conform to, the tortuous and diametrically varying configuration of a fistula tract **10** when expanded within the fistula tract. Thus, once the body **13** is allowed to expand within the fistula tract, the device generally completely fills the fistula tract.

In certain embodiments, when the body **13** expands to fill the fistula tract, the device may generally stop, resist or slow fluid flow from the bowel from running out through the fistula tract. The device may do this by occluding the distal end of the tract via a distal end of the device body **13** that is generally non-porous or has an ability to seal the distal end of the tract. However, generally speaking, a fistula tract will leak fluid from within the tissue walls surrounding the fistula tract. Some of this fluid will be absorbed by the device. The remaining fluid will drain out of the proximal end of the tract, potentially through the proximal end of the device body **13**, which is generally porous or has the ability to allow the passage of fluids while generally occluding or filling the tract.

The time to closure and the necessity for surgery may be reduced (e.g., significantly) by preventing or reducing bodily fluids that originate at the distal end of the tract (e.g., bowel fluids) from passing through a fistula tract **10** and, in some embodiments, also by reducing the amount or rate of flow through the fistula tract for body fluids originating in the tract itself. In certain embodiments, the devices **5** disclosed herein may reduce or eliminate the passage of fluids through the tract **10** while also providing a matrix that promotes tissue growth. The devices **5** may be utilized to treat a variety of clinically significant fistulas **10**, as appropriate, including enterocutaneous fistulas, anal fistulas, bronchopleural fistulas, non-healing g-tube tracts, tracheal-esophageal fistulas, and others.

Referring again to FIGS. **1**A and **1**B, the device **5** is depicted as located in a fistula tract **10** in a compressed or non-expanded state (FIG. **1**A) and in a non-compressed or expanded state (FIG. **1**B). The device **5** includes a proximal end **31**, a distal end **32**, and the expandable body **13**, which is formed of a plurality of individual porous bodies **15** operably connected via a connecting member **20**. Each porous body **15** includes a proximal end **25** and a distal end **30**. Additionally, each porous body **15** is adapted to expand from a compressed or non-expanded state (FIG. **1**A) to a non-compressed or expanded state (FIG. **1**B) after insertion into the tract **10**, thereby filling any cavities within the tract **10** and approximating the fistula tract walls.

As can be understood from FIG. **1**A, in some embodiments, when the bodies **15** are in a compressed or non-expanded state, the bodies **15** will be spaced apart from each other along the length of the device **5**, thereby forming a segmented configuration for the device body **13**. In some embodiments, the spaced-apart distances D between adjacent proximal and distal ends **25**, **30** of the bodies **15** in a compressed or non-expanded state is between approximately zero mm and approximately five mm. In one embodiment, the spaced-apart distances D between adjacent proximal and distal ends **25**, **30** of the bodies **15** in a compressed or non-expanded state are between approximately zero mm and approximately 25 mm. Where the distance D between immediately adjacent bodies **15** is approximately zero mm when the bodies **15** are in a non-expanded state, the bodies **15** will be said to be in an abutting or touching configuration, as opposed to a spaced-apart condition. Regardless, the device body **13** will still be considered to be segmented on account of the device body **13** being formed of a plurality of individual porous bodies **15**.

In some embodiments, the spaced-apart distances D between adjacent proximal and distal ends **25**, **30** of the bodies **15** in a compressed or non-expanded state are between approximately zero percent and approximately two and one-half percent of the overall non-expanded length L of a body **15**. Where the distance D between immediately adjacent bodies **15** is approximately zero percent of the length L of a body **15** when the bodies **15** are in a non-expanded state, the bodies **15** will be said to be in an abutting or touching configuration, as opposed to a spaced-apart condition. The device body **13** will still be considered to be segmented, however, on account of the device body **13** being formed of a plurality of individual porous bodies **15**.

Regardless of whether the bodies are in a spaced-apart configuration or an abutting or touching configuration when the bodies **15** are in the compressed state, the segmented configuration of the device body **13** facilitates the device body **13** being inserted in and conforming to the tortuous diametrically varied route formed by the tract **10**.

As can be understood from FIG. **1**B, when the bodies **15** are fully expanded within the tract **10**, the spaced-apart distances D' between adjacent proximal and distal ends **25**, **30** of the bodies **15** in a non-compressed or expanded state may be between approximately zero mm and approximately five mm. In some embodiments, the spaced-apart distances D' between adjacent proximal and distal ends **25**, **30** of the bodies **15** in a non-compressed or expanded state may be between approximately zero percent and approximately two and one-half percent of the overall expanded length L' of a body **15**. The expansion of the bodies **15** after insertion into the fistula tract **10** allows the device body **13** to approximate the walls of the fistula tract, as well as fill open cavities. Because the segmented configuration of the device body **13** allows the device to closely conform to the tortuous and diametrically varied route formed by the tract **10**, the bodies **15**, when in an expanded state within the tract **10**, generally fill the tract **10** in a manner that minimizes voids and dead space. Minimizing voids and dead space lowers the chance of sepsis and other complications.

While a segmented body **13** has been described, some embodiments of tissue treatment devices may comprise a non-segmented body (i.e., a body **13** that is a continuous, single-piece body **13** as opposed to being formed from multiple bodies **15**).

Any suitable methods may be used to deliver or deploy the fistula treatment devices described herein.

In one embodiment, and as illustrated in FIGS. **10**A-**10**F, the device **5** may be loaded in a lumen of a catheter, sheath or guidewire. As can be understood from FIGS. **10**A and **10**B, the loaded catheter or sheath **900** or guidewire (not shown) is then inserted into the tract **10**. Next, and as shown in FIG.

10C, the loaded catheter or sheath **900** or guidewire is withdrawn from about the device body **13** to leave the device body **13** within the tract **10**. As indicated in FIGS. **10C-10F**, the device body **13** then softens and/or expands to fill and occlude the tract **10**. As illustrated in FIG. **10F**, a proximal clip **1000** may be used at the proximal end of the device **5** to further secure the device **5** in the tract **10**. Other proximal members may alternatively or additionally be used, as appropriate, and as discussed in more detail below.

In another embodiment, and as shown in FIGS. **9A-9C**, the catheter or sheath may be a dual lumen catheter **900**, where one lumen contains the device **5** and the other lumen contains a guidewire **901**. In certain embodiments, the catheter may be a multi-lumen catheter where at least one lumen is shaped like a "D". In some embodiments, a delivery device may include a central or main lumen through which the fistula closure device **5** may pass and a secondary lumen through which the guidewire **901** may pass. As can be understood from FIGS. **9A** and **9B**, the guidewire **901** is inserted into the fistula tract **10** and the catheter **900** is tracked over the guidewire **901**. As shown in FIG. **9C**, the device **5** is deployed and the catheter **900** is withdrawn from about the device body **13** to leave the device body within the tract **10**. The device body **13** then expands to fill and occlude the tract **10**.

In some embodiments, a catheter comprising a peel-away sheath may be used. For example, a skive, score, partial cut, mechanical joint or formed groove may create a longitudinally extending stress concentration for causing the catheter to peel along the stress concentration.

In certain embodiments, the delivery device **900** may be tracked over a guidewire **901** with the fistula occlusion device **5** residing in the main lumen. Once properly positioned in the fistula tract, the delivery device **900** can be removed from about the closure device **5**. The removal of the delivery device **900** from about the closure device **5** may be accomplished by grasping an exposed portion of the delivery device **5** or a grasping member, for example, and then pulling or pushing the delivery device relative to the closure device **5**. Alternatively, a hooked member having a hook or other engagement feature that engages an end of the delivery device **900** may be employed where the hooked member can be used to pull the delivery device **900** from about the closure device **5**.

In other embodiments, the device **5** may be deployed via a guidewire with a hook-like feature at one end. Such a delivery device can be used for an anal fistula **10**, where there is access at both a proximal and a distal end of the fistula tract **10** (in contrast to an enterocutaneous fistula, which has one external access point). The guidewire with the hook-like feature may be inserted into the fistula tract at a first end and passed through the tract **10** such that it can be used to pull the device **5** through the tract **10** by the hook to a second end. The distal end of the device **5**, which may already be in an expanded state, may anchor the device **5** into the fistula tract. This embodiment of the delivery device may reduce the amount of work required of the surgeon as the hook may be used to pull the delivery device into place. In an additional embodiment, a guidewire or stylet may be extended through the device body **13** generally parallel to the connecting member **20**. In other words the device body **13** may be threaded onto the guidewire or stylet. The guidewire or stylet may then be used to negotiate the device body **13** into the tract **10**. Once positioned in the tract **10**, the stylet or guidewire may be withdrawn from the device body **13**. Where the device body **13** is threaded onto the stylet or guidewire, the bodies **15** may have holes therein for receiving the stylet or guidewire. Also, the bodies **15** may have slots through their sides that lead to the holes so the stylet or guidewire can be inserted into the holes without having to be placed therein via a threading motion. In versions of such embodiments, the slots and/or holes in the bodies **15** for receiving the stylet or guidewire in a threaded arrangement are configured to close after the stylet or guidewire is withdrawn from the bodies **15**. The closure of the slots and/or holes may result from the expansion of the bodies **15**.

Regardless of whether a catheter, sheath, guidewire or stylet or combination thereof is used to deploy the device **5** in the tract **10**, once located within the tract **10**, the device body **13** will begin to expand and fill the voids of the tract **10**. Expansion of the bodies **15** may be a result of being free of the constraints of the lumen of the sheath, catheter or guidewire used to deliver the device **5**. Expansion of the bodies **15** may be a result of being free of the constraints of a restraining mechanism such as a biodegradable ring, sheath, member, etc. extending about the bodies **15** when first deployed in the tract **10**. Expansion may be a result of being exposed to body fluids or temperature within the tract **10**. Expansion may be a result of any one or more of these aforementioned expansion methods.

As can be understood from FIG. **1B**, the porous bodies **15** at the proximal and/or distal ends **31**, **32** of the device **5** may be configured to protrude from the distal and/or proximal fistula openings when implanted in the fistula tract **10**. As depicted in FIG. **1B**, the protruding end **115** of the most distal body **110**, or the entirety of the most distal body **110**, may be configured to expand more than the rest of the porous bodies **15**. Such an over-expanding capability at the distal ends **32** of the device **5** when within the fistula tract may produce an occluding and anchoring effect. Additionally or alternatively, the same concept may be applied to the most proximal body **15** at the device proximal end **31**. Such embodiments can be considered to have at least one body **15** with a magnitude of expansion that is different from (i.e., exceeds) the magnitude of expansion of the other bodies **15**. In one embodiment, a device **5** with a distal most body **110** that is configured to have increased expansion as compared to its fellow bodies **15** will be positioned in the tract **10** such that the most distal body **110** is partially within the tract **10** and partially extending from the distal opening **12** into, for example, the bowel lumen. Thus, as illustrated in FIG. **1B**, once the distal portion of the device **5** is in place, the distal most body **110** of the device **5** expands to contact the edges of distal opening **12** of the fistula tract **10**, thereby occluding the distal opening **12** of the fistula tract **10**. The device **5** also expands to fill the rest of the fistula tract **10**. To facilitate a generally complete sealing of the distal opening **12**, the distal most body **110** of the device **5** may include an impermeable coating.

In a manner similar to that discussed above with respect to the distal most body **110**, the proximal most body at the proximal end **31** of the device **5** may be adapted and configured to anchor or otherwise hold the device **5** in place within the fistula tract. Where both the distal and proximal most bodies are so configured, the distal and proximal most bodies will provide a counter force or counter balance to each other through the connecting member **20**. In some embodiments, the proximal most and/or distal most bodies may be or include an adhesive layer to further strengthen the seal around the respective fistula tract openings.

For a discussion of distal most or proximal most bodies **15** having shapes other than generally cylindrical, reference is made to FIGS. **1C** and **1D**, which are respectively the same as FIGS. **1A** and **1B**, except illustrating the differently shaped bodies **15**. As shown in FIGS. **1C** and **1D**, the distal most body **120** may have a shape that is non-cylindrical and, more specifically, conical. While not shown here, in some embodi-

ments, the proximal most body **15** at the proximal end **31** of the device **5** may also have a conical shape as opposed to a cylindrical shape.

In some embodiments, the conically shaped most distal body **120** is generally shaped such that its distal end **125** is generally greater in diameter than its proximal end. The distal end **32** of the device **5** may be advanced into the distal opening **12** of the fistula tract **10** such that a distal portion **125** of the body **120** extends from the tract opening **12** into, for example, the bowel lumen. As illustrated in FIG. **1**B, once the distal end of the device **5** is in place, the distal end **125** of the body **120** expands to contact the edges of the distal opening **12** of the fistula tract **10**, thereby occluding the distal opening **12** of the fistula tract **10**. The rest of the device body **13** also expands to generally fill the rest of the fistula tract **10** as described above. In some embodiments, the proximal end **31** of the device **5** does not extend beyond the edge of the fistula tract, while in other embodiments it does.

In some embodiments, the difference in diameter of the distal end **125** could be a result of a difference in the distance by which the different parts of the distal body **120** can expand. For example, the diameter of the cylinder in the compressed or non-expanded state is uniform; however, when the cylinder expands, the proximal end of the cylinder may reach the wall of the fistula tract **10**, while the distal end may have a greater distance to expand before reaching the wall of the fistula tract **10** which corresponds to its target area of expansion. In this case, the diameter of the cylinder in a non-expanded state is uniform, but the diameter of the cylinder in the expanded state forms a conical shape.

In FIGS. **2**A and **2**B, the device body **13** is similar to that discussed above with respect to FIGS. **1**A and **1**B, in that the device body **13** includes individual porous bodies **15** (delivered here by a delivery catheter **280**) coupled together via a connecting member **20**. However, here, and as indicated in FIGS. **2**A and **2**B, the distal end **32** of the device **5** terminates in an expandable member **200**, which is coupled to the distal end of the connecting member **20**. The expandable member **200** serves to anchor the device distal end in place at the fistula distal opening **12** and/or to seal the fistula distal opening **12**.

The expandable member **200** may have any appropriate configuration, and in some cases may include a gel-filled or otherwise readily deformable member sandwiched between a pair of generally rigid discs. In some embodiments, the expandable member **200** may be shaped like a wagon wheel, with the outer rim being the sealing part and the spokes helping to distribute air and/or any other suitable inflation fluids. The expandable member **200** may, for example, comprise a generally flat and circular configuration, or may be thicker and non-circular, including oval or rectangular shaped devices. Although the expandable member **200** is depicted as comprising a generally planar configuration, in other variations, the expandable member may comprise a concave proximal surface and a convex distal surface, which can resiliently deform toward a flattened or everting configuration

The expandable member **200** may be configured to be collapsed for delivery to the target location and to re-expand when deployed. In some examples, the expandable member **200** may comprise a resilient material that re-expands upon removal of any restraint acting on the collapsed body, such as the removal or withdrawal of a delivery catheter, or the cessation of suction or vacuum acting on the collapsed body. For example, the body may be molded (e.g., injection or blow molded) using polyurethane, polyvinyl chloride or any other suitable resilient polymeric material into its base configuration that may then be collapsed using suction or vacuum. In some examples, the expandable member **200** may comprise a shape-memory or superelastic material, including but not limited to nickel-titanium alloys or shape-memory polymers. In other examples, re-expansion may be facilitated by the infusion or inflation of a liquid or gas into the expandable member **200**. The expandable member **200** may generally comprise any suitable material or materials. For example, in some cases the expandable member **200** may comprise one or more biocompatible polymers and/or one or more biodegradable or bioabsorbable materials. Expandable members are described, for example, in U.S. Patent Application Publication No. US 2010/0228184 A1, which is incorporated herein by reference in its entirety.

As shown in FIG. **2**A, the delivery catheter **280** may be advanced (e.g., over a suture) to the target site. In some cases, the delivery catheter **280** may be advanced to the target site through a sheath (not shown). Once the distal end of the delivery catheter **280** is positioned at the target site, an actuator (not shown) may be inserted into the delivery catheter **280** until it is positioned against the proximal most expandable member **15**. The position of the actuator may then be maintained while the delivery catheter **280** is proximally withdrawn to deploy the expandable members **15** into the fistula tract **10**. The actuator and the delivery catheter **280** may then be proximally withdrawn from the sheath. It should be understood that this is only one example of a delivery method, and other suitable delivery methods may also be used, as appropriate.

In some embodiments, the expandable member **200** may comprises at least one inflatable balloon, chamber or cavity. The inflatable balloon may, for example, be advanced in a non-inflated state through the distal opening **12** of the fistula tract **10**. Once in position, the balloon may be inflated (e.g., via a lumen in the connecting member **20**) with a material such as air or saline, or another biocompatible fluid or solidifying gel. The balloon may be a fluid-inflatable or expandable disc-shaped balloon adapted to occlude the distal tract opening. Alternatively, the balloon may be a fluid-inflatable or expandable flat cone-shaped balloon adapted to occlude the distal tract opening. Other suitable shapes or configurations may also be used, e.g. a curved configuration with a distal convex surface and a proximal concave surface, as mentioned earlier. Tension may then be applied to the device **5** via the connecting member **20**, to thereby cause the balloon to occlude the distal opening **12** of the fistula tract **10**. In some variations, the expandable member **200** may be sufficiently resilient to achieve its expanded configuration when any collapsing force or structure is removed, but wherein the inflation chambers may be used to alter the resiliency, rigidity or other mechanical characteristics of the expandable member.

In some embodiments, one or more actuation mechanisms may be used to expand the expandable member **200**, while in other embodiments, the expandable member **200** may be expanded without any actuation mechanisms. For example, the expandable member **200** may expand upon exposure to body fluids or a temperature differential within the tract **10**, or via its own biased nature. In addition to the expandable member **200** expanding to anchor the device **5**, the device body **13** expands to generally fill the rest of the fistula tract **10** as described above, and as depicted in the progression from FIG. **2**A to FIG. **2**C.

In some embodiments of a fistula closure device **5** equipped with an expandable member **200**, the device **5** and its expandable member **200** in a non-expanded state are configured to pass through a lumen of catheter size of nine French or smaller, and in some embodiments, twenty French or smaller.

In certain embodiments, the expandable member **200** may comprise an adhesive coating adapted to adhere to the tissue surface of the region adjacent the distal opening **12** of the fistula tract **10**, while in other examples, the adhesive may be light curable, where the light is provided via a fiberscope inserted into the fistula tract (with or without the delivery tool or a cannula in place), or in some variations, via the lumen of the gastrointestinal tract. The adhesive may activate after exposure to a fluid (e.g., body fluid) or body temperature. The adhesive may initially strengthen the bond of the member **200** to the tissue and then gradually degrade in strength as fistula tract healing occurs or after fistula tract healing. Depending on the embodiment, the adhesive may create a fluid impermeable seal for at least 7, 14, 21, 28, 35, 60 or any other number of days.

In certain embodiments, an expandable member **200** may include attachment members, such as micro hooks or tines. Such attachment members may be located on a surface of the expandable member **200** intended to contact the tissue surface area forming the opening **12**, thereby facilitating the adherence of the expandable member to the tissue surface bordering the distal tract opening and the occlusion thereof.

In some embodiments, an expandable member **200** or various components thereof may be resorbable and adapted to occlude the fistula tract and then resorb after the tract **10** has closed at least about 45%, 55%, 65%, 75%, 85%, 95%, 100% or any other percentage. The expandable member **200** or various components thereof may be biodegradable and/or adapted to fall away from the distal fistula opening **12** and be extruded through the gastrointestinal tract. For example, the expandable member **200** or various components thereof may be secreted from the body after the tract **10** has progressed towards closure (e.g., after at least 7, 14, 21, 28, 35 or any other number of days adequate to achieve sufficient closure).

In some embodiments, the connecting member **20** may be a biocompatible polymer string extending through the tract from the expandable member **200**. The connecting member **20** may be formed of one or more resorbable materials and may resorb after the tract **10** has closed at least about 45%, 55%, 65%, 75%, 85%, 95%, 100%, or a percentage range between any two of the above percentages. The connecting member **20** may provide tensile force substantially perpendicularly to the expandable member **200**, thereby pulling the expandable member **200** against the tract's distal opening **12** and anchoring the expandable member **200** in place to occlude the distal tract opening.

Expandable members or components **200** may have any suitable shape or configuration, and may be actuated using any appropriate mechanism. In some cases, a plugging mechanism may be used to seal an expandable member **200** (e.g., after the expandable member has been positioned at a target site and expanded). For example, FIGS. **3**A and **3**B show an expandable member **200** coupled to a connecting member **20** (e.g., that may be used for loading one or more porous bodies **15**), where a plug member **300** is used to seal the expandable member when it is expanded. As shown, the plug member **300** comprises a plug portion **302** and an elongated member **304** (e.g., a suture) coupled to or integral with the plug portion. The expandable member **200** in this embodiment comprises a disc-shaped portion **306** and a tip portion **308**, although other configurations may also be used. In FIG. **3**A, the expandable member **200** has not yet been sealed. However, in FIG. **3**B, the plug member **300** has been actuated to move the plug portion **302** into the tip portion **308** of the expandable member, and to thereby seal an aperture **310** in the tip portion. The plug member **300** may be actuated, for example, by proximally withdrawing the elongated member **304** (i.e., in the direction of arrow **312**). While not depicted here, in certain embodiments, it may also be possible to undo the seal (e.g., by pushing on the elongated member **304** and thereby disengaging the plug portion **302** from the tip portion **308**).

FIGS. **5**A-**5**C similarly depict the sealing of an embodiment of an expandable member **200**. First, as shown in FIG. **5**A, the expandable member **200** has been delivered to the target site, but is not yet sealed. The delivery catheter **500** engages ribs **502** of the tip portion **308** of the expandable member **200** and thereby stabilizes the position of the expandable member **200**. In some embodiments, the expandable member **200** may be expanded by injecting inflation fluid in the proximal end of the delivery catheter **500**, such that the inflation fluid travels through the delivery catheter **500** into the expandable member **200** and thereby inflates the expandable member **200**.

In FIG. **5**B, the elongated member **304** has been proximally withdrawn to move the plug portion **302** into the aperture **310** in the tip portion **308** of the expandable member **200**. This positions the plug portion **302** in the sealing position, where it seals the expandable member **200**. As shown, the plug portion **302** now engages ribs **506** of the tip portion **308** of the expandable member **200**. Finally, FIG. **5**C shows the sealed expandable member **200**, when the delivery catheter **500** has been disengaged therefrom (e.g., by being proximally withdrawn).

While plug members comprising elongated members and plug portions have been described, other embodiments of plug members having different components and/or configurations may also be used, as appropriate. For example, a plug member may comprise multiple plug portions and/or a plug portion having a different configuration.

Once the expandable member **20** has been expanded, it may be used to seal the distal opening of a fistula tract. FIG. **4** depicts the actuation of a delivery instrument **1550** (shown in its entirety in FIG. **15**B), by pulling on the tether **1424** in the direction of arrow **402**, to tension the tether and thereby seal the distal opening of the fistula tract **10** with expandable member **20**. While one actuation mechanism is shown, other appropriate actuation mechanisms may alternatively or additionally be used.

As discussed above, in some embodiments of the device **5**, the proximal end of the device may be adapted and configured to receive a proximal clip that secures the device in place. The clip may, for example, be disc-shaped, or may have a different (e.g., polygonal) shape. The clip may be made of any biocompatible material, such as PGLA, PVA or PVC, or any other suitable biocompatible polymer or plastic. The material may also be resorbable. In use, the clip may extend across the proximal end of the fistula tract **10** and may be generally flush or slightly raised relative to the proximal end of the fistula tract **10**. The clip may help to maintain tension on the connecting member **20** that couples the expanding member **50** with the clip, thereby helping to maintain or anchor the device **5** in the tract **10**. The clip may be coupled to the connecting member **20** in any appropriate fashion, such as via friction, pinching, suturing or any other suitable method.

Features of the clip and/or proximal end **31** of the device **5** may be transparent to allow visual inspection of the tract. In some embodiments, the clip and/or proximal end of the device may be adapted to cover the proximal end of the fistula tract without completely sealing the proximal end of the tract, thereby allowing accumulating fluids to drain or escape from the proximal end of the tract. In some cases, the clip may comprise a mesh-like membrane that permits drainage of

accumulating fluids from the proximal end of the tract. After the tract **10** heals, the proximal clip may resorb or otherwise be removed.

Referring back to FIGS. **2**C-**2**F, in addition to effectively anchoring the distal end of a device **5** (as shown, using an expandable member **200**), the proximal end of a device may also be stabilized or positioned with a proximal anchor **250**.

In FIGS. **2**C-**2**F, tethers **254** and **256** that are attached to the expandable member **200** may be used to apply tension to the expandable member **200** to thereby seal the fistula tract **10**. In some examples, at least one of the tethers (e.g., tether **256**) may be provided to as a guide element for delivery of the expandable members **15** of the body **13** along the fistula tract **10**. At least one or both of the tethers **254** and **256** may be secured using the proximal anchor **250**. This securing of the tethers **254** and **256** makes distal sliding or displacement of one or both of the tethers less likely, as the proximal anchor **250** provides an increased surface area or transverse dimension that resists collapse or entry of the proximal anchor **250** into the fistula tract. The proximal anchor **250** may help to maintain the tension in one or both of the tethers **254** and **256**.

In use, the proximal anchor **250** may be slid onto one or both of the tethers and positioned adjacent the skin surface (e.g., after the expandable members **15** have been expanded in the fistula tract **10** by, for example, infusing saline into the fistula tract). While maintaining tension on the tension tether **254** through the proximal anchor **250**, the delivery tether **256** may be sutured or otherwise attached to the surrounding tissue using a free needle passed through the proximal anchor **250** and tied to the tissue with the desired tension. At a location opposing the delivery tether **256** on the proximal anchor **250**, a free needle may be used to pass through the proximal anchor **250** and to suture the tension tether **254** to the surrounding tissue. Additional sutures (e.g., 3-0 or 4-0 nylon) may be used to further secure the proximal anchor **250** to the surrounding superficial tissue as needed.

The size and shape of the proximal anchor **250** may depend, for example, upon the particular fistula being treated. In some embodiments, the proximal anchor **250** may have a diameter or maximum transverse dimension that is at least the same as that of the expandable member **200**. In further examples, the diameter or maximum transverse dimension may be at least two times, three times, or four times or greater than the corresponding dimension of the expandable member **200**. The expandable member **200** and the proximal anchor **250** may both have the same shape (e.g., circular) or may have different shapes.

The proximal anchor **250** may also comprise one or more securing apertures **258** that may permit the attachment of the proximal anchor **250** to the skin or a bandage surrounding the dermal fistula opening. These securing apertures **258** may be spaced around the periphery of the proximal anchor **250**, closer to the outer edge rather than the center of the proximal anchor **250**. Any suitable number of apertures having any appropriate size may be used. In other examples, the proximal anchor **250** may comprise an adhesive surface that contacts the skin surrounding the fistula and resists movement. The tethers **254** and **256** of the device may be secured to the proximal anchor **250** by any of a variety of mechanisms, including a clamping structure, adhesive, or by a deformable slit that provides a releasable friction fit interface for the tethers **254** and **256**. The attachment site of the tethers **254** and **256** on the proximal anchor **250** may further comprise access openings that may be used to infuse therapeutic agents into the fistula, and/or to permit passive or active fistula drainage, or the application of negative pressure therapy to the fistula.

FIG. **2**C depicts a proximal anchor **250** comprising just a single body **259**. However, in FIGS. **2**D and **2**E, the proximal anchor **250** is depicted as comprising a first portion **260** and a second portion **262** that is movably coupled to the first portion by a plurality of resilient members **264**. The first portion **260** is the more distal portion of the proximal anchor **250**, and may have a tissue contact surface **266** that is configured to resist passage into a fistula of the type being treated (e.g., an entero-cutaneous fistula). The first portion **260** also comprises an aperture **267** that permits slidable coupling to at least one tether (e.g., tethers **254** and **256**). The second portion **262** is the more proximal portion of the proximal anchor **250**, and comprises a tether-fixing structure **268** configured for affixation of at least one tether (e.g., tethers **254** and **256**) thereto. For example, at least one tether may be tied to the tether-fixing structure **268**.

During use, when the first and second portions **260**, **262** are coupled to a tether, the first and second portions can move relative to each other to accommodate changes in the length of tether between them. For example, movement by the patient may necessitate having a lesser or greater length of tether between the first and second portions. The ability of the first and second portions to move relative to each other may allow for such a change to take place without, for example, resulting in tether breakage or excessive tether slackness. While the first and second portions **260**, **262** of the proximal anchor **250** of FIGS. **2**D and **2**E are allowed to move relative to each other as a result of the resilient members **264**, in other embodiments, different portions of a proximal anchor **250** may be movably coupled to each other in other ways, as discussed in additional detail below.

It should be noted that any of the proximal anchors described herein may be configured to allow for negative pressure transmission (e.g., negative pressure wound therapy), as appropriate. For example, the proximal anchors may include one or more apertures configured for negative pressure wound therapy. A vacuum pump may be applied to suction out fluid and/or collapse dead space to facilitate healing.

FIGS. **6**A-**6**C provide enlarged views of the proximal anchor **250** comprising first and second portions **260**, **262**. As shown in FIG. **6**B, proximal anchor **250** has an overall height **292**, first portion **260** has dimensions **290** and **294**, and second portion **262** has dimensions **296** and **298**. In some embodiments, overall height **292** may be from about 0.25 inch to about 0.75 inch, dimension **290** may be from about 0.5 inch to about 1.5 inches, dimension **294** may be from about 0.1 inch to about 0.5 inch, dimension **296** may be from about 0.15 inch to about 0.5 inch, and/or dimension **298** may be from about 0.05 inch to about 0.25 inch. Proximal anchor **250** may be made of any suitable material or materials, including but not limited to polymers, metals (e.g., titanium) and/or metal alloys (e.g., stainless steel). First and second portions **260**, **262** may comprise the same material or materials, or may comprise different materials. In certain embodiments, resilient members **264** may comprise one or more metal alloys, such as Nitinol.

Referring to FIG. **2**E, in some cases, an absorbent dressing **270** may be positioned securely on top of the proximal anchor **250** to absorb any excess drainage that may occur. Alternatively, active drainage of the fistula/wound may be performed using wound drainage products or negative pressure wound therapy products. In certain cases, a proximal anchor may be configured both to accommodate negative pressure wound therapy and to accommodate an absorbent dressing. Also, prophylactic antibiotics may be optionally provided post-procedure. In some cases, and referring now to FIG. **2**F, a

protective cap **272** (e.g., that may be relatively rigid) may be provided over the proximal anchor **250**. The protective cap **272** may, for example, be formed of one or more polymers, metals and/or metal alloys. As shown, the protective cap may comprise at least one vacuum port **274** (e.g., to allow for negative pressure wound therapy).

FIGS. **7**A and **7**B show an alternative embodiment of a proximal anchor **250**, in which the direction of force is parallel with the skin surface. In other words, here the tether is tensioned with a force that generally is not directed outward from the body. Drag on the tether may be reduced by using a large radius for the transition in which the tether changes direction during use. The embodiment shown in FIGS. **7**A and **7**B has an interlocking design that advantageously would minimize the space required to accommodate a relatively long tether length, while still allowing for tether movement. More specifically, in FIGS. **7**A and **7**B, the proximal anchor **250** comprises a frame member **700** and first and second portions **702**, **704** that are slidably coupled to the frame member and that are configured to interlock with each other. While one interlocking configuration is shown, other configurations (e.g., using different interlocking shapes) may also be used, as appropriate.

The first and second portions **702**, **704** of the proximal anchor **250** comprise protruding members or pegs **706** through which at least one tether (here, the tension tether **254**) may be routed. Additionally, the proximal anchor **250** comprises a tether clamp **711** that may be used to lock or secure the tether **254** at a proximal location **715**. During use, the first and second portions **702**, **704** may slide away from each other (in the directions of arrows **706**, **708**) and toward each other, to accommodate for variations in the length of tether extending from the skin surface. For example, in FIG. **7**A, a relatively short amount of the tether **254** extends from the skin surface. However, as shown in FIG. **7**B, when a greater length of the tether **254** extends from the skin surface, the proximal anchor **250** can accommodate for the difference without decreasing the tension in the tether. Similarly, the length of the tether **254** extending from the skin surface may become shorter without resulting in breakage of the tether. While not shown, in some cases a cover may be positioned over this proximal anchor **250** (e.g., to prevent interference from clothing, blankets, negative pressure wound therapy, or the like).

As discussed above, methods described herein employ expandable members **15** to fill a fistula tract. Different expandable members **15** and arrangements thereof may be used with the devices, methods and kits described herein, as appropriate. FIG. **11** shows just one example of a device body **13** comprising expandable members **15** coupled together with a suture **1100**. Additionally, FIG. **12** shows a delivery catheter **280** comprising a tubular member **1202** and expandable members **15** disposed within the tubular member **1202**. The delivery catheter **280** may be used to deliver the expandable members **15** to a target site.

In some embodiments, the expandable members **15** of the device **5** may comprise porous bodies. For example, the expandable members **15** may comprise a compressed open cell polymer and may be made of any synthetic or natural biodegradable, resorbable, biocompatible polymer or polymers, such as collagen, hyaluronic acid and polyglycolic acid ("PGA"). The biodegradability may allow for degradation at a specified rate that matches the rate of tissue ingrowth and fistula tract healing, such that by the time the fistula tract is healed, the material is completely absorbed by the body. It should be noted that in some cases, the fistula tract may heal before the material is completely absorbed by the body. That is, the degradation rate of the device may not match, or may be slower than, the rate of tissue ingrowth and fistula tract healing.

Expansion of the bodies **15** within the tract **10** provides a porous scaffold to the fistula tract and may partially or entirely stop the flow of bodily fluids through the tract. The scaffold provides a matrix that may promote tissue in-growth, allowing the fistula to close. In certain embodiments, one or more antimicrobial agents, such as silver, may be incorporated in the porous bodies **15** and/or in the insertion methodology to actively prevent infection and/or sepsis formation and aid in the healing of the tract. The porous bodies **15** may include wound-healing agents, such as growth factors. In some embodiments, the porous bodies may include fibrosis-promoting agents.

A porous body may be adapted and configured to expand after placement in the fistula tract and to absorb fluid, thereby approximating closely the tract intra-luminal walls. In some embodiments, a porous body may include a porous resorbable open cell polymer foam adapted to expand and serve as a scaffold for tissue growth and closure of the fistula tract.

In certain embodiments, a porous body may comprise collapsed or compressed pores, adapted and configured to increase in size after placement in a fistula tract, thereby filling the fistula tract. In some embodiments, the pores of the bodies may advantageously be of a reduced size. For example, pore size may vary from 5 to 1000 microns with an overall porosity of 25-95%. In certain embodiments, bodies with a controlled pore size (i.e., without a broad distribution of pore sizes) of between approximately 50 microns and approximately 100 microns may be used. A body with a controlled pore size may promote greater angiogenesis, which, in turn, may promote better wound-healing. Examples of materials that may provide some or all of the controlled pore size and porosities include various biomaterials manufactured by Kensey Nash Corporation, CollaPlug® or other collagen products as manufactured by Integra Corporation, and STAR® materials as manufactured by Healionics Corporation.

In some embodiments, the fluid permeability (i.e., porosity or pore size) of the bodies **15** may increase from the distal end of the device **5** to the proximal end of the device **5**. For example, a first body **15** at the distal end of the device **5** may have a lower fluid permeability than other bodies **15** of the device **5**. That is, in a segmented body **13**, a most distal body **15** or the most distal several bodies **15** (i.e., the single body **15** or the few multiple bodies **15** in closest proximity to the distal end of the tract, e.g., at the bowel end of the tract) may have the lowest fluid permeability and the bodies **15** extending proximally away from the most distal body **15** may have a higher fluid permeability. In certain embodiments, the fluid permeability of the bodies **15** proximal to the most distal body or bodies **15** may increase from body to body, moving in the proximal direction. A most distal body **15** or bodies **15** with a lowest fluid permeability may further enhance occlusion of the distal end **12** of the fistula tract **10** and prevent unwanted fluid from the bowel from entering the fistula tract. The bodies **15** proximal of the most distal body **15** or bodies **15** may have a higher fluid permeability to permit drainage of fluids accumulating in the tract and to promote tissue ingrowth to facilitate healing of the fistula tract.

A non-segmented body **13** may have a fluid permeability (i.e., porosity or pore size) that changes along its length. For example, the distal portion of the non-segmented body **13** may have a lower fluid permeability as compared to the proximal portion.

The porous bodies **15** may be in the form of polymer members that are anisotropic. For example, in some embodiments, the polymer members **15** may be anisotropic such that they have substantial radial expansion, but minimal, if any, longitudinal expansion.

In certain embodiments, the porous bodies **15**, when in a compressed or non-expanded state, may have a volume that is significantly less than the volume of the bodies **15** when in a non-compressed or expanded state. For example, in some embodiments, the compressed or non-expanded volume of the bodies **15** may be between approximately 10% and approximately 60% of the non-compressed or expanded state volume. In certain embodiments, the compressed volume may be between approximately 20% and approximately 25% of the expanded volume. As a result, the bodies **15** may expand between approximately four and approximately five times their compressed volumes when expanding from a compressed state to an expanded state. For example, a body **15** with a porosity of 80% can be compressed to 20% of its expanded state. In other words, the body **15** may expand approximately five times its compressed volume when expanding from a compressed to a non-compressed state. The body **15** may expand even more if it retains any absorbed fluid from the fistula tract **10**.

The porous bodies **15**, when in a compressed or non-expanded state, may be relatively easy to insert in a fistula tract **10** and may cause less damage upon insertion due to the reduced size. The compressed porous bodies **15** also may allow for controlled expansion. In other words, the expanded size of a compressed porous body **15** is generally known and may be chosen and optimized based upon the configuration of the fistula tract **10**. Thus, use of a compressed porous body **15** may permit greater occlusion of the fistula tract **10** because the compressed porous bodies **15** conform to the tract **10**, as opposed to making the tract **10** conform to the body of the device. The porous bodies **15** also may not require fluid to expand or to be maintained in an expanded state. Such controlled expansion porous bodies **15** may be formed of hyaluronic acid, hyaluronic acid mixed with collagen, or any other suitable materials that offer control or specific pore size or porosity.

In some embodiments, the controlled expansion of the bodies **15** may be a function of precompressing the bodies **15** a certain extent (e.g., approximately 80 percent of their non-compressed state) and then releasing the bodies **15** to resume their non-compressed state. Thus, it is possible to readily determine the final fully expanded condition of the bodies **15** because they may only expand to their non-compressed state upon being released to resume the non-compressed state.

As mentioned above with respect to FIG. **1**A, the porous bodies **15** of the device **5** may be operably connected by a connecting member **20**. The connecting member **20** may be a bioresorbable and biocompatible filament or string, for example. In certain embodiments, the connecting member **20** may also be a filamentous string, which enables the decoupling of the plurality of porous bodies **15** from the connecting member subsequent to implantation of the device **5** in the tract **10**.

As shown above in FIGS. **1**A and **1**B, in some embodiments, the device **5** may include at least two porous bodies **15**. The bodies **15** may be adapted and configured to work together to form the device's overall body **13** and separately to allow the device body **13** to conform to the tract **10** and fill all of the tract voids. In other words, the bodies **15** may be separate individual bodies joined together via the connecting member **20** along the length of the device **5**, such that the resulting device body **13** has a segmented configuration. In certain embodiments, when the bodies **15** are in an expanded state or even in a non-expanded state, the spaced-apart distances D, D' may be zero, such that the proximal and distal ends **25**, **30** of adjacent bodies **15** abut. In such an embodiment, the bodies **15** may appear to form a generally continuous porous device body **13** that is segmented by the interfaces of the adjacent proximal and distal ends **25**, **30** of adjacent bodies **15**. Thus, regardless of the magnitude of the spaced-apart distances D, D', in some embodiments, the device body **13** can be considered to be a chain or series of individual porous bodies **15** configured to work together and separately, resulting in an overall body **13** of the device **5** that is segmented and capable of conforming to the tract **10**. It should be noted that the device **5** does not stent open the tract **10**, but rather, the device **5**, when in an expanded or non-compressed state, is capable of conforming to the tract **10**.

In some embodiments, the device **5** may be configured to fill multi-tract fistulas. For example, the device **5** may comprise multiple device bodies **13** joined together at a common point of the device **5**. In other words, the device may have at least two chains of porous bodies **15** joined together to allow a segmented device body **13** to be inserted into each of the tracts **10** of a multi-tract fistula. Alternatively, at least two chains of porous bodies **15** may be joined together to create a device **5** with at least two segmented device bodies **13**.

In certain embodiments (not shown), the porous bodies **15** may also include attachment members that are configured to attach and engage the bodies **15** with the tract **10**, and that deploy when the bodies **15** are in a non-compressed or expanded state. The attachment members may be unidirectional (e.g., comparable or similar to a fish hook barb) or may have a compressed fishbone-like structure and may be made of any appropriate biocompatible, resorbable material. The attachment members may permit outward removal but not inward traction. That is, when the attachment members are deployed, the bodies **15** may be retracted towards the proximal end without damaging the fistula tract **10**, but the bodies **15** may be engaged with the tract **10** such that they will not migrate towards the distal end **12** of the tract **10**.

As can be understood from FIG. **9**B, in one embodiment, the device **5** may be deployed from the lumen of a delivery sheath or catheter **900** via a long, flexible rod or a "pusher" **903**. The pusher **903** may be inserted through the delivery device **900** and may enable the clinician to push or otherwise direct the segmented device body **13** into the tract **10**, thereby minimizing the dead space or void that may be left between the individual segments of the device body **13** or between the body **13** and tract **10**. In some embodiments, the porous bodies **15** may not be connected via a connecting member **20**, but instead may be multiple free bodies **15** that are inserted into the lumen of the sheath **900** for delivery into the tract. Thus, a pusher may enable the clinician to push or otherwise direct the unconnected bodies **15** into the fistula tract **10**.

In certain embodiments, the bodies **15** of the fistula closure device **5** may be formed from materials other than a graft, wherein graft is defined as a transplant from animal or human tissue.

In some embodiments, the bodies **15** of the fistula closure device **5** may be formed from materials other than an extracellular matrix ("ECM") material, wherein ECM material is defined as decellularized organic tissue of human or animal origin. Furthermore, in some such embodiments, the bodies **15** of the fistula closure device **5** may be formed from materials other than those that are remodelable, where remodelable is defined as the ability of the material to become a part of the tissue. Instead, in some embodiments, the bodies **15** of the fistula closure device **5** may rely heavily on the amount of

induced cross-linking that allows control of the resorption rate. Cross-linking essentially destroys the remodelable properties of a material. While remodelable may not exclude resorbable material completely, in some embodiments, the bodies **15** of the fistula closure device **5** may be formed of material that is completely resorbable and has no remodelable requirements or capabilities.

In some embodiments of the fistula closure device **5**, the device body **13** may be formed of multiple bodies **15** to form a segmented body **13**. The body **13** may include a distal occlusion member **200** (e.g., an umbrella-like member), the member **200** acting as an occlusion mechanism that is more of an occlusive cover rather than a plug or sealing member.

The fistula closure devices **5** as described herein may be implanted into a fistula tract **10** via various methods. For example, the fistula tract **10** may be visualized via direct visual inspection or medical imaging methods (e.g., Fluoroscopy, CT scan, MRI, etc.). A guidewire may be negotiated through the tract **10**. The tract **10** may then be de-epithelializing irrigated. The device **5** may then be threaded over the guidewire and pushed into the tract **10**. The distal fistula opening **12** may be occluded via elements of the device **5** (e.g., the most distal body **110** and/or expandable member **200**). The device **5** may be trimmed to the length of the tract **10**, after which the guidewire is removed. The device **5** and, more specifically, the device body **13**, may be irrigated to cause expansion of the body **13**. The device **5** may be anchored at the proximal fistula opening with a proximal end piece. For example, a retaining member may be connected to the distal end of the device **5** and secured to the region surrounding the proximal end opening of the tract **10**, thereby creating tension in the device **5**. The proximal fistula opening may then be covered with a dressing.

In another method of implanting the fistula closure device **5** in a fistula tract **10**, a compressed porous scaffold **13** is placed in the fistula tract **10**, wherein the scaffold **13** is at least partially inserted into the tract **10**. The porous scaffold may be filled with, for example, an injectable polymer fluid, which may form an occlusive plug and may promote tissue growth and hence healing of the fistula tract. The method may further include fixating the device **5** in the tract **10** using a biocompatible connecting member **20**, such as a string, which is attached to the device **5**. The polymer injected into the tract **10** may be in a form that allows the foam to approximate the walls of the fistula tract **10** and fill any voids in the tract.

In another method of implanting the fistula closure device **5** in a fistula tract **10**, a distal end **32** of the device **5** may be placed in such a way as to protect and occlude the distal end **12** of the fistula tract **10**. The body **13** of the device **5** may be inserted into the fistula tract **10** in such a way as to at least partially fill the fistula tract **10**. The surface load or point load dependent expansion of porous bodies **15** may then be activated within the fistula tract and the device **5** may be anchored in place at the distal and/or proximal ends **32**, **31**. For purposes of this disclosure, surface load or point load dependent expansion refers to the expansion of the porous bodies where, upon contact between the fistula tract wall (the "load") and a point on the porous body, that point of the porous body will stop expanding. The points on any or all of the rest of the porous body will continue to expand until the remaining points also make contact with the fistula tract wall. Thus, the surface load or point load dependent expansion of the bodies **15** of the device **5** disclosed herein allows the body **13** to generally fill and conform to the tract **10** without distorting the tract **10** or causing the tract to conform or deform due to the expansion of the body **13** in the tract. This ability of the body **13** can be a result of pre-compression of the body **13** and/or the nature of the material used.

Examples of materials from which to form the bodies **15** of the device **5** include: AngioSeal-like products, collagen sponge or other biomaterial materials as manufactured by Kensey Nash Corporation (Exton, Pa.); CollaPlug® or other collagen products as manufactured by Integra Corporation (Plainsboro, N.J.); and STAR® materials as manufactured by Healionics Corporation (Redmond, Wash.). With respect to the CollaPlug® material, in some embodiments, the CollaPlug® material may be compressed prior to delivery into the tract **10**, the CollaPlug® material being approximately 90% porous. With respect to the STAR® materials, some such materials are known to have a specific pore size that promotes better angiogenesis. The STAR® materials and some of the materials and products discussed above may be capable of achieving a desirable controlled pore size and overall porosity for purposes of the devices and methods disclosed herein.

In another method of implanting the fistula closure device **5** in a fistula tract **10**, the tract may be visualized and a guidewire may be routed into the tract. The tract **10** may be de-epithelialized and irrigated to remove any unwanted internal matter. The fistula closure device **5** may be tracked over the guidewire and the device **5** may then be received into the fistula tract until the distal end of the device **5** extends beyond the distal fistula opening **12**. The device **5** may be expanded by irrigation so as to approximate the fistula tract **10**. The device **5** may be trimmed if required. The method may include clipping or otherwise securing the proximal end of the device **10** at the proximal tract opening to provide a secure anchor. The proximal opening may then be covered with a dressing. In one embodiment, the segmented body **13** of the device **5**, when in an expanded state, generally approximates the volume of the fistula tract with minimal distortion of the fistula tract.

FIGS. **13A-13C** depict another example of a fistula closure device, comprising a generally disc-shaped sealing body **1302** having a proximal surface **1304**, a distal surface **1306** and an outer side wall **1308** therebetween. To facilitate sealing of the fistula tract, the proximal surface **1304** of the sealing body **1302** may comprise a seal **1310**. In the depicted example, the seal **1310** is located along the peripheral edge of the sealing body **1302**, but in other examples may be spaced away from the edge. The seal **1310** depicted in FIG. **13A** comprises an annular configuration, but in other examples, the seal may have a polygonal, oval, star or square shape, for example, that may be the same or different shape as the sealing body **1302**. The seal **1310** may be solid or may comprise a hollow interior. In some instances, a hollow interior may facilitate collapse of the sealing body **1302** for delivery, or facilitate deformation or conformation to the shape of a target location.

As further depicted in FIG. **13A**, the sealing body **1302** may also comprise one or more ribs or support structures **1312**. The number of support structures **1312** may be in the range of about one to about ten or more, from about two to about eight, about three to about six, or about five support structures, for example. The support structures **1312** may be evenly or symmetrically spaced apart in a radial configuration with respect to the center of the sealing body **1302** or a midline of the sealing body **1302**. The support structures **1312** may also be solid or hollow. In some examples comprising at least one hollow support structure **1312** and a seal **1310** that is at least partially hollow, the support structure **1312** and the seal **1310** may be in fluid communication through an access lumen **1314** provided on the sealing body **1302**. The access lumen **1314** may permit injection or filling of materials into

the body **1302**, including but not limited to contrast agents (e.g. barium, contrast saline, etc.) or a bulking material such a silicone. The distal surface **1306** may be generally smooth, which may facilitate passage of materials through the gastrointestinal tract past the implanted sealing body **1302**, but in other examples may comprises one or more recesses, openings and/or projections. The proximal surface **1304** may comprise recesses **1316** located between the support structures **1312** and/or the annular seal **1310**. In some embodiments, the recesses may reduce the degree of surface contact between the sealing body **1302** and the surrounding tissue, thereby shifting sealing forces along the annular seal **1310**.

The sealing body **1302** may further comprise an attachment structure **1320** to facilitate delivery of the sealing body **1302**. The delivery catheter, if any, may releasably engage the sealing body **1302** at the attachment structure **1320**. The attachment structure **1320** may also be the attachment site for one or more tethers or sutures that may be used in conjunction with the sealing body **1302**. In some further examples, the attachment structure **1320** may be located centrally with respect to the overall shape of the sealing body **1302**, but in other examples the attachment structure **1320** may be eccentrically located. The attachment structure **1320** may be integrally formed with the access lumen **1314**, or may be separate from the access lumen, which may be used to inject materials into the hollow lumens and/or cavities of the support structures **1312** and the annular seal **1310**, if any. In other examples, through lumens in the body may permit access to the intestinal lumen for fluid sampling, placement of sensors, and/or therapeutic agent delivery.

Referring to FIG. **14**, the sealing body **1302** may be a distal portion of a fistula closure device. In use, the sealing body **1302** may seal the fistula tract by tensioning the sealing body **1302** against the intestinal wall of a patient though one or more tethers **1424** and **1426** attached to the sealing body **1302**. The tethers **1424** and **1426** may be attached at the attachment structure **1320** or other location of the sealing body **1302**, including but not limited to the annular seal **1310** and/or the support structures **1312**. The multiple tethers **1424** and **1426** may be color coded to distinguish the various tethers during the implantation procedure. At least one of the tethers **1424** may be used to apply tension to the sealing body **1302** and seal the fistula tract. In some examples, a second tether **1426** may be provided to as a guide element for delivery of the expandable members. In some embodiments, providing separate tethers **1424** and **1426** may reduce the risk of free-floating or unsecured expandable members **1428** should the tensioning tether **1424** rupture. FIG. **14**, for example, depicts the second tether **1426** that may be used to deploy one or more expandable members **1428** along the fistula tract. At least one or both of the tethers **1424** and **1426** may be secured using a proximal restraining structure **1430** that resists distal sliding or displacement of the tether **1424** and/or **1426** by providing an increased surface area or transverse dimension that resists collapse or entry of the restraining structure **1430** into the fistula tract.

It should be understood that features and characteristics described herein with reference to specific expandable members **200** and sealing bodies **1302** may be applied to any of the other expandable members and sealing bodies described herein, as appropriate.

As shown in FIG. **14**, the expandable members **1428** may comprise generally elongate collagen plugs (or other biocompatible material) that are configured to expand, fill and conform to surrounding tissue structures. The plugs may have a generally cylindrical shape, but in alternative examples may have any of a variety of shapes, including spheres, rectangular blocks, conical or frusto-conical shapes, and the like. Not all of the plugs need to have the same size, shape, orientation and/or symmetry. As further illustrated in FIG. **14**, the expandable members **1428** may be interconnected by a plug suture or tether **1432**. The plug tether **1432** may form a loop structure **1434** at one end of the plurality of expandable member **1428** that may facilitate delivery of the expandable members **1428** along at least one of the tethers **1426**. The expandable members **1428** may be slidably attached or fixedly attached to the plug tether **1432** by a resistance interfit, but in other examples, one or more expandable members **1428** may have an enlarged tether lumen to facilitate sliding or other relative movement with respect to the plug tether **1432**. In still other examples, one or more expandable members **1428** may be glued to the tether, or the plug tether **1432** may have a cross-over configuration or stitching through the expandable member to resist relative movement or separation of the expandable member. For example, in some, all or at least the distalmost or free-floating expandable member, the plug tether **1432** may be fixedly attached using any of a variety of attachment interfaces described above. In some further examples, the plug tether **1432** may further comprise one or more knots or other fixedly attached structures along its length to limit sliding or movement of an expandable member to a particular range.

In one exemplary delivery procedure, the fistula tract and surrounding area may be prepped and draped in the usual sterile fashion. Anesthesia may be achieved as needed using topical and/or injectable anesthetics. The fistula tract may then be irrigated with sterile saline, hydrogen peroxide or any other suitable biocompatible irrigation fluid. In some further examples, portions of the fistula tract may be de-epithelialized using silver nitrate sticks, cautery and/or mechanical debridement using a scalpel, for example. The delivery instrument may be removed from its aseptic packaging and placed onto a sterile field. To reduce the risk of dislodging the sealing body **1302**, tensioning of the attached sutures **1424** and **1426** may or may not contraindicated. Various extension tubes and stopcocks, if any, may be attached to the delivery instrument **1550** at this time. Flushing, patency/leakage testing of the delivery instrument connections may be performed using saline or similar fluid. The integrity of the sealing body **1302** may also be assessed using saline, contrast agent or a mixture of both and the application of positive and/or negative fluid pressure through the delivery instrument **1550**. Prior to delivery, the sealing body **1302** may be evacuated with negative pressure to collapse the sealing body **1302**. The same or a separate syringe of saline, contrast agent or combined fluid may be prepared as an inflation syringe for the sealing body.

The fistula tract may be traversed using a guidewire, with or without the assistance of imaging modalities such as plain X-ray, fluoroscopy, CT scanning, endoscopy, or ultrasound, for example. The peel-away sheath may be passed over the guidewire and through the dermal ostium of the fistula tract. A dilator may be used as needed to prepare the fistula tract for passage of the delivery instrument and/or endoscopic instrument. The position of the sheath may be verified with the same or different imaging modality. The procedure may be continued once the desired sheath tip location is achieved or verified, e.g. the distal tip is located beyond the intestinal or central ostium of the fistula tract. The guidewire (and dilator, if any) may then be removed. The sheath may be flushed with sterile saline. The collapsed sealing body **1302** may be wrapped around the distal end of the delivery instrument **1550** by rolling, rather than collapsing the sealing body **1302** like an umbrella. The delivery instrument **1550** may be inserted

into the sheath and advanced until the sealing body **1302** is located beyond the distal tip of the sheath. The relative location of the delivery instrument **1550** may be evaluated by imaging, by the distance between proximal ends of the sheath and delivery instrument, and/or by the loss of insertion resistance that may be tactilely felt once the sealing body **1302** has exited the sheath. A 10 cc syringe, for example, may be attached to the delivery instrument and negative pressure may be applied to the sealing body **1302** through one of the stopcocks, which then may be closed to maintain the sealing body **1302** in a collapsed state. The syringe may then be removed and is replaced with a syringe of the same or smaller size. The stopcock is re-opened and the evacuation of the sealing body **1302** may be confirmed by pulling back on the syringe and assessing plunger displacement. A portion of the fluid in the syringe (e.g. 0.5 cc) may then be injected into the sealing body **1302** to inflate it. The stopcock may be closed to maintain the inflation.

While maintaining the position of the delivery catheter (or the Touhy Borst valve), gentle traction may be applied to the tension tether attached to the sealing body **1302** to fully seat the sealing body **1302** to the delivery instrument **1550**. The Touhy Borst valve may then be loosened and the sheath may be partially retracted into the fistula tract (e.g., proximal to the central ostium). The sealing body **1302** may then be deployed by disengaging or otherwise separating the lock mechanism between the Touhy Borst valve **1562** and the connector **1556**. The remaining distal portions of the delivery instrument **1550** may then be slowly withdrawn from the fistula tract. While maintaining slight tension on the tension tether **1424** to hold the sealing body **1302** against the central ostium of the fistula tract, the sheath may be slid proximal the desired length that is to be filled with the expandable members. Slight tension may be maintained on the tension tether **1424** through the remaining procedure until the tether is anchored to the skin.

The actuator **1572** may be inserted into the plug delivery catheter **1570** until the suture loop **1434** just exits the distal end **1578** of the catheter **1570**. The actuator **1572** may then be withdrawn. While maintaining slight tension on the tension tether **1424**, the delivery tether **1426** may be threaded through the loop **1434** at the distal end **1578** of the delivery catheter **1570**. The catheter **1570** may then be advanced over the delivery tether **1426** until the catheter tip **1578** is located at the desired delivery location. The actuator **1572** may be reinserted into the catheter **1570** until the distal end **1574** of the actuator **1572** contacts the most proximal expandable member **1428** in the catheter **1570**. The position of the actuator **1572** may then be maintained while the delivery catheter **1570** is retracted to deploy the distalmost expandable member **1428**. The catheter **1570** may or may not be relocated to deploy the remaining expandable members **1428**. Once deployment of all the expandable members **1428** is completed, the Luer fittings on the proximal end **1576** of the delivery catheter **1570** and actuator **1572** may be engaged and the catheter **1570** and actuator **1572** may be removed from the sheath. Saline may be optionally infused through the sheath to facilitate expansion of the expandable members **1428**. Using separately supplied catheters **1570** and actuators **1572**, additional expandable members may be deployed using the above procedure to fill the fistula to the desired level. Sealing body **1302** placement may be reconfirmed by imaging techniques to ensure that the sealing body **1302** is located against the central ostium.

While maintaining tension on the tension tether **1424**, the restraining structure **1430** may be separated from the sheath and the sheath may be removed from the fistula tract. While continuing to maintain slight tension on the tension tether **1424** through the restraining structure **1430**, the delivery tether **1426** may be sutured or otherwise attached to the surrounding tissue using a free needle passed through the restraining structure and tied to the tissue with the desired tension. At a location opposing the delivery tether **1426** on the restraining structure **1430**, a free needle may be used pass through the restraining structure **1430** and to suture the tension tether **1424** to the surrounding tissue. Additional sutures (e.g., 3-0 or 4-0 nylon) may be used to further secure the restraining structure **1430** to the surrounding superficial tissue as needed. Final imaging confirmation of the sealing body **1302** placement along the central ostium may be performed at this point using the imaging modalities as previously described, but also including double-contrast x-ray studies and colonoscopy/enteroscopy. An absorbent dressing may be securely on top of the restraining structure **1430** to absorb any excess drainage that may occur. Alternatively active drainage of the fistula/wound may be performed using wound drainage products or negative pressure wound therapy products. Prophylactic antibiotics may be optionally provided post-procedure.

The size and shape of the restraining structure **1430** may be different depending upon the particular fistula being treated, but in some examples, the restraining structure **1430** may have a diameter or maximum transverse dimension that is at least the same as the sealing body **1302**. In further examples, the diameter or maximum transverse dimension may be at least two times, three times, or four times or greater than the corresponding dimension of the sealing body **1302**. The restraining structure **1430** may also comprise one or more securing apertures **1436** that may permit the attachment of the restraining structure **1430** to the skin or a bandage surrounding the dermal fistula opening. These securing apertures **1436** may be spaced around the periphery of the restraining structure **1430**, closer to the outer edge rather than the center of the restraining structure **1430**. In other examples, the restraining structure **1430** may comprise an adhesive surface that contacts the skin surrounding the fistula and resists movement. The tethers **1424** and **1426** of the device may be secured to the restraining structure **1430** by any of a variety of mechanisms, including a clamping structure, adhesive, or by a deformable slit **1438** that provides a releasable friction fit interface for the tethers **1424** and **1426**. The attachment site of the tethers **1424** and **1426** on the restraining structure **1430** may further comprise access openings **1440** that may be used to infuse therapeutic agents into the fistula, and/or to permit passive or active fistula drainage, or the application of negative pressure therapy to the fistula. FIG. **15**A depicts the restraining structure **1430** without the attached tethers.

Referring to FIG. **15**B, positioning of the sealing body **1302** and tethers **1424** and **1426** may be performed using a delivery instrument **1550** that comprises an elongate tubular element **1552** that is configured with a distal end **1554** that releasably attaches to the attachment structure **1320** of the sealing body **1302**. The interface between the attachment structure **1320** and the tubular element **1552** may comprise a resistance interfit, but may alternatively comprise a mechanical interlocking fit such as a helical threaded interface, for example. In some embodiments, attachment of the sealing body **1302** to the tubular element **1552** may also be provided by tensioning the tether **1424** that passes through the tubular element **1552** and other portions of the delivery instrument **1550**. To prepare the sealing body **1302** for delivery, the sealing body **1302** may be collapsed or compressed around the distal end **1554** of the tubular element **1552** and held in that configuration using a cannula or introducer. In some examples, applying suction or a vacuum may facilitate col-

lapse of the sealing body **1302**. Although delivery of the sealing body **1302** may be performed through the fistula tract and toward the gastrointestinal site, in other examples, the cannula or introducer may be configured to pierce tissue so that delivery instrument **1550** may be used to deliver the sealing body **1302** and at least one tether **1424** along a secondary tract other than the fistula tract. This secondary tract may be a pre-existing tract or a tract formed by the insertion delivery instrument.

As shown in FIG. **15**B, other features of the delivery instrument **1550** may include one or more connectors **1556**, **1564** that permit the attachment or use of access lines **1558** and stopcocks **1560**, **1566**, for example, which may facilitate the aspiration or infusion of materials, or the insertion of endoscopic tools or sensors during the delivery procedure. The delivery instrument **1550** may include a hemostasis valve **1562** or other fluid-sealed interface that permits passage of items such as the tether **1424** while resisting fluid leakage.

The expandable members **1428** may be provided in a rigid or flexible tubular catheter **1570**, as depicted in FIG. **15**D. To expel or release the expandable members **1428**, a push element or actuator **1572**, depicted in FIG. **15**C, may be used to serially release the expandable members **1428** from the distal end **1578** of the catheter **1570**. This may be performed by pushing the distal tip **1574** of the actuator **1572** through the proximal end **1576** of the catheter **1570** while holding the catheter **1570** in place, or by holding the actuator **1572** in place while withdrawing the catheter **1570**, for example.

To perform the procedures described above, a kit may be provided that contains the delivery instrument **1550** along with the sealing body **1302** and attached tethers **1424** and **1426**. The sealing body **1302** and attached tethers **1424** and **1426** may be coupled to the instrument **1550** at the point-of-manufacture or at the point-of-use, and therefore may be provided in the kit either pre-attached or separate from the instrument **1550**. The kit may also comprise an actuator prefilled catheter **1570** with one or more expandable members **1428** that are pre-attached with a plug tether **1430**. Additional catheters **1570** with expandable members **1428** may be also be packaged and provided separately. In further examples, the kit may also contain one or more other items, including but not limited to a guidewire (e.g. 0.038" guidewire), a peel-away sheath (e.g. 7F, 8F, 9F, 10F, or 12F sheath), one or more syringes (e.g. 0.5 cc, 1 cc, 5 cc, and/or 10 cc syringes), saline or biocompatible fluid, contrast media, a scalpel, one or more free needles, and non-resorbable sutures (e.g. 3-0 or 4-0 nylon suture) that may be used to attach the restraining structure **1430** to the adjacent skin or to a bandage. A fistula tract dilator may also be provided in the kit.

Fistula treatment devices described herein may in some cases be provided in a kit. The kit may also include any other appropriate devices or components, such as delivery tools or other fistula treatment devices (i.e., a kit may include multiple fistula treatment devices). The contents of a kit may be provided in sterile packages. Instructions may be provided on or with the kit, or alternatively via the internet or another indirect method, and may provide direction on how to employ the kit (e.g., outlining a deployment method such as one of those described herein).

FIG. **8** depicts an exemplary kit **800**. As shown there, the various components of the fistula closure device **5** are provided in a sterile package **802**. For example, the sterile package **802** may contain the connecting member **20**, the expandable member or distal anchor **200**, the proximal anchor **250**, and individual porous bodies **15** for threading over the connecting member **20**. Instructions **804**, which may be provided on or with the kit **800**, or alternatively via the internet or another indirect method, provide direction on how to employ the kit. The instructions may, for example, outline a deployment method similar to those described above. It should be understood that the concept of kits may readily be applied to any of the devices and device components disclosed herein, as appropriate.

FIGS. **16**A and **16**B depict another example of a distal anchor **1600** for occluding a distal opening of fistula tract. As depicted therein, distal anchor **1600** may comprise a plurality of foldable members **1602**, **1604**, **1606**, and **1608** threaded on a suture **1610**. FIGS. **16**A and **16**B illustrate, respectively, an expanded and a restrained configuration of distal anchor **1600**. The expanded configuration illustrated in FIG. **16**A may represent the configuration of the distal anchor **1600** when it has been released from an insertion device into a body lumen. The restrained configuration illustrated in FIG. **16**B may represent the configuration of the distal anchor when a restraining force is exerted on the distal anchor **1600** by tensioning the suture **1610** while the distal anchor **1600** is positioned over a distal opening of a fistula tract. As can be appreciated by comparing FIGS. **16**A and **16**B, flexible members **1604**, **1606**, and **1608** are configured to slide along suture **1610**. Proximal-most foldable member **1608** may be further configured to occlude a distal opening of the fistula tract. Distal-most foldable member **1602** may be configured to reduce or prevent rupturing at the center of foldable member **1608** when the suture **1610** is tensioned during positioning of the distal anchor **1600**. Distal-most foldable member **1602** may be configured to a size and shape that distributes the force exerted by the suture over a wider area—the area of contact between foldable member **1602** and the next foldable member, first inner foldable member **1604**. In this way, pressure exerted on foldable member **1608** by tensioning suture **1610** can be reduced. Inner foldable members **1604** and **1606** may also serve to reduce or prevent rupturing of the proximal-most foldable member **1608** by further distributing the force exerted on foldable member **1608**. Distal-most foldable member **1602** may also comprise a suture attachment structure **1612** for attaching suture **1610**.

Each foldable member comprises a large dimension (diameter) and a small dimension (thickness). In some variations, the diameter is considerably larger than the thickness. For example, the foldable members of distal anchor **1600** comprise a very large diameter relative to their thickness so that the foldable members take on a "pancake" appearance. In some variations, the small dimension of the foldable members are characterized as percentages of the large dimension, and may sometimes be less than or equal to 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, 15%, 20%, 30%, 40% or 50%, or any percentage range between any two of the above percentages. The foldable members are configured so that the large dimension is oriented generally in parallel to a surface of a body lumen when the foldable members are deployed.

In some variations, the foldable members may reduce in diameter from the proximal-most foldable member **1608** to the distal-most foldable member **1602**. The diameter of the distal-most foldable member may be characterized as a percentage from 1% to 100% of the diameter of the proximal-most foldable member **1602**, and may sometimes be about 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%, or any percentage range between any two of the above percentages. In other variations, the diameter difference may be approximately equal to a percentage between any of the foregoing percentages. The diameters of the inner foldable members **1604** and **1606** may also be characterized as a percentage from 1% to 100% of the diameter of the proximal-most foldable member

**1602**, and may sometimes be about 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%, or any percentage range between any two of the above percentages. In other variations, the diameter difference may be approximately equal to a percentage between any of the foregoing percentages. In some variations, the diameter of the proximal-most foldable member may be sized to occlude a distal opening of a fistula tract. In some variations, the diameter of the proximal-most foldable member may be in the range of about 4 mm to about 50 mm, sometimes about 8 mm to about 30 mm, and other times about 10 mm to about 45 mm, and still other times about 12 mm to about 30 mm. Further, although four foldable members are illustrated in FIGS. **16**A and **16**B, other variations may include any number of foldable members, including 2, 3, 5, 6, 7, 8, 9, 10 foldable members.

In some variations, one or more of the foldable members are non-circular. A non-circular outline can be understood to be any shape in which the perimeter is not a constant radius from a center point. Non-circular shapes include shapes with first-derivative discontinuities at one or more locations. Non-circular shapes may also be Non-circular shapes may also be Non-circular shapes a generally circular shape with protrusions or recesses on the perimeter to accommodate a predetermined surface of a body lumen. Non-circular shapes may include, but are not limited to, ovals, ellipses, rectangles, lenses, deltoids, and bell-shapes. When non-circular, a diameter of a foldable member may be understood to mean a length of the member in one dimension. For example, a line taken through a center point or a widest span of the member. In such variations, the diameters of the distal-most and inner foldable members may be characterized as a percentage from 1% to 100% of the diameter of the proximal-most foldable member, and may sometimes be about 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, some of the foldable members take a shape different from one or more of the other foldable members. For example the distal members may be circular, but the proximal-most foldable member may be shaped to occlude a non-circular fistula opening. In some other variations, the distal foldable members are also non-circular in order to achieve a desired distribution of forces, for example.

Suture attachment structure **1612** is illustrated on a distal surface of foldable member **1602**, but in some variations is positioned on a proximal surface of distal-most foldable member **1602**. When on the distal surface, the suture attachment structure may comprise an aperture to allow the suture to pass through the foldable member and an additional feature to fixedly couple the suture to the foldable member. When positioned on the proximal surface, the suture attachment structure may include a loop or other feature to fixedly couple the suture to the foldable member. In some variations, the suture attachment structure includes a recess on the distal surface of the distal-most foldable member **1602**. Distal-most foldable member **1602** may also comprise reinforcing structure (not shown) for the suture attachment structure **1612**. In some variations, the reinforcing structure is a wire mesh embedded within distal-most foldable member **1602** and configured to distribute the force resulting from tensioning the suture across all or some of the distal-most foldable member **1602**. In other variations, the reinforcing structure might include a button-shaped suture attachment structure, wherein the expanded areas of the button-shaped suture attachment structure serve to distribute the force over a wider area.

In some variations, the foldable members **1604**, **1606**, and **1608** may include apertures (not shown) to permit the members to slide along suture **1610**. Although illustrated in FIGS. **16**A and **16**B as passing through the center of the foldable members, in some variations the suture does not pass through the centers of one or more foldable members. For example, when the surface of a distal opening of a fistula tract does not lie in a plane orthogonal to the axis of the fistula tract, tensioning of the suture may cause an unequal distribution of force on the proximal-most disk. In such a scenario, the apertures may be off-center to redistribute the forces to provide an even, reduced pressure on the proximal-most foldable member. In some variations, the apertures may be reinforced by a ring or grommet. The reinforcement structure, if any, may be fully embedded with the foldable member, or may be partially exposed on either the distal and/or proximal surface of the member. In some further variations, the reinforcement structure may also comprise an interlocking structure to interlock with a complementary interlocking structure of the reinforcement structure of an adjacent foldable member. Other examples of inter-member locking features are described below.

As described above, the foldable members **1602**, **1604**, **1606**, and **1608** are configured to be released from an insertion device. In some variations, the foldable members are configured to be reduced in size to fit within an insertion rod of a given diameter. For example, one or more of the foldable members may be configured to reduce its cross-sectional profile by folding or rolling, thereby facilitating entry into the insertion rod, as described in more detail later. In some variations, the flexibility of the foldable members may be increased as the diameters increase to facilitate folding or rolling of the foldable members to a predetermined cross-sectional profile for insertion. In some variations, a flexibility of a foldable member may be characterized by a thickness of the foldable member. In some variations, a flexibility of the foldable members may be characterized by its percentage thickness, from 1% to 100%, of the thickness of the distal-most foldable member, and may sometimes be about 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, a flexibility of the foldable members may be characterized by its percentage density, from 1% to 100%, of the density of the distal-most foldable member, and may sometimes be about 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%, or any range between any of the two percentages. In some variations, a flexibility of the foldable members may be characterized by its percentage coefficient of resistance to deformation, from 1% to 100%, of the coefficient of resistance to deformation of the distal-most foldable member, and may sometimes be about 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the flexibility of a foldable member may be constant across the member. In other variations, the flexibility of a foldable member may vary across the member by, for example, a variance in the density and/or thickness in different regions of the foldable member. This flexibility variance may be controlled to facilitate folding the member or to facilitate coupling two foldable members.

Foldable members **1602**, **1604**, **1606**, and **1608** are depicted in FIGS. **16**A and **16**B as generally planar. In some variations, the foldable members are non-planar. For example, the foldable members may be generally concave. A concave geometry may advantageously distribute pressure in

a predetermined field when the foldable members are fully restrained. A generally concave shape may also reduce the propensity of the distal anchor to pucker and result in a central region of the distal anchor lying proximal to an outer region when the distal anchor is in the deployed configuration. When the distal anchor is in the deployed configuration, a relatively large quantity of pressure may focus in the central region of the distal anchor, possibly resulting in a structural fracturing of the distal anchor at the central region. A concave geometry may also advantageously limit the distal anchor's re-entry into the fistula tract as a result of puckering, that is, may limit the propensity of a central region of the distal anchor to lie proximal to an outer region when the distal anchor is fully restrained. The generally concave geometry of the foldable members may be characterized by a cross-sectional curve with a zero first derivative when the foldable member is rotated 90 degrees clockwise (that is, when the foldable member is turned on its side). When rotated back 90 degrees anti-clockwise, the zero first derivative may be located at a proximal-most or distal-most point of the curve. FIGS. **17**A and **17**B illustrate side views of two exemplary sets **1700** and **1720**, respectively, of generally concave foldable members with zero first derivatives at the proximal-most and distal-most points of the curve, respectively. FIG. **17**A depicts a side-view of a set **1700** of foldable members **1702**, **1704**, **1706**, and **1708** with zero first derivatives located at the proximal-most point of the curves, that is, the geometry of the cross-sections of the foldable members forms a reverse "C." Foldable members **1702**, **1704**, **1706**, and **1708** are slidably connected by suture **1710**. FIG. **17**B depicts a side-view of a set **1720** of foldable members **1722**, **1724**, **1726**, and **1728** with zero-derivatives located at the distal-most point of the curves, that is, the geometry of the cross-section foldable members forms a "C." Foldable members **1722**, **1724**, **1726**, and **1728** are slidably connected by suture **1730**. Although each foldable member depicted in FIGS. **17**A and **17**B comprises a constant radius of curvature, some variations may include one or more foldable members with a non-constant radius of curvature. Such shapes may include, but are not limited to, a bell, a cone, a mushroom head, or a box. In some variations, the geometry of a foldable member may be characterized as a 180 degree revolution of a curve about a line through a point of zero first derivative. For example, the geometries illustrated in FIGS. **17**A and **17**B may be generated by rotating an arc of fixed radius about its minimum point of zero first derivative. In other variations, the geometry may be defined by rotating a parabolic curve about a point of zero first derivative, wherein a parabolic curve is defined by the equation $y=Cx^2$, where (x, y) comprise a range in a Cartesian plane and C is any real, non-zero number. In other variations, the geometry may be defined by a rotating the two-dimensional polynomial equation $y=\Sigma a_n x^n$, where (x, y) comprise a range in a Cartesian plane, $a_n$ is any real number, and n is any integer.

Although the geometries described above are generated by a single curve defining both the distal and proximal surface of each foldable member—that is, the foldable member has a constant thickness—other variations may have different curves to respectively define the proximal and distal surfaces. Further, although the curves above are discussed with respect to an (x,y) Cartesian plane, it should be understood that the cross-section of the foldable member may not be positioned in a fistula tract so that the curve remains in that orientation. For example, although a cross-sectional area of a foldable member may be described in (x,y) coordinates so that its first derivatives are at the top or bottom of a curve, in some variations, the foldable member is rotated for insertion so that the minimum point is now at a vertical mid-point.

Further, the curves and shapes described above refer to a general or overall shape of a foldable member, the foldable members may have additional surfaces features. For example, a foldable member's overall shape may be augmented with any of the recesses, protrusions, and coupling members described herein.

As depicted in FIGS. **17**A and **17**B, the relative curvature of the foldable members increases from the proximal-most foldable member to the distal-most foldable member, that is, the radius of curvature decreases from the proximal-most foldable member to the distal-most foldable member. In some variations, the radius of curvature of the distal-most foldable member and inner foldable members may be characterized as a percentage, from 1% to 100%, of the radius of curvature of the proximal-most foldable member, and may sometimes be about 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the curvature decreases from the proximal-most foldable member to the distal-most foldable member, that is, the radius of curvature increases from the proximal-most foldable member to the distal-most foldable member. In some variations, the radius of curvature of the proximal-most foldable member and inner foldable members may be characterized as a percentage, from 1% to 100%, of the radius of curvature of the distal-most foldable member, and may sometimes be about 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In other variations, the curvature of the members may be constant. A variation in curvature among the foldable members may be determined to account for a variation in flexibility among the foldable members. For example, a less flexible member may be more likely to resist deformation when fully restrained and so less curvature may be necessary. A variation in curvature among the foldable members may also be determined to account for a variation in pressure exerted on the foldable members in the restrained configured and its effect on each foldable member's relative deformation. For example, a more distal foldable member is likely to deform more due to the pressure being exerted more directly on that member. In some variations, the unrestrained curvature of each foldable member may be determined to generate a predetermined shape of the distal anchor in the restrained configuration. That is, the curvature of the unrestrained foldable members may be determined so that a predetermined shape is achieved once all the foldable members are restrained and coupled to each other. In some variations, the predetermined shape is planar. In others, the predetermined shape is non-planar. In some variations, the curve may be a bell-shape curve so that the revolved curve may include outside edges with a lower curvature than a central region. In other variations, the curve may include outside edges with a higher curvature than a central region. Also, although the exemplary embodiments depicted herein comprise multi-member distal anchors that generally comprise a reduced member size from proximal to distal, in other variations, the members may be generally of the same size, and may or may not vary in curvature from proximal to distal, as described above.

Returning to FIGS. **16**A and **16**B, foldable members **1602**, **1604**, **1606**, and **1608** are depicted as being generally smooth on their distal faces. In some variations, one or more foldable members include additional features to restrict relative movement of the foldable members in a direction generally transverse to the direction of the force exerted by the suture. In some variations, movement is restricted by surface features

on one or more foldable members that fixedly couple the one or more foldable members to adjacent foldable members. In other variations, a pair of adjacent foldable members include electromagnetic elements that produce attractive electromagnetic forces, such as opposing magnetic poles, that fixedly couple the adjacent foldable members. In other variations, an adhesive may be used to fixedly couple the one or more foldable members to adjacent foldable members. For example, one surface of a foldable member may include an adhesive or complementary interconnecting structures, including but not limited to hook-and-loop attachment structures. In some variations, one surface of a foldable member may comprise a curing agent. In yet further variations, the curing agent may be enclosed in one or more capsules, where the capsule is configured to rupture open exposure to an agent included on the opposing surface of the adjacent foldable member. In other variations, the capsule may rupture as a result of the pressure exerted when the distal anchor is restrained by a suture.

In some variations, the proximal surface of the proximal-most foldable member may be structured to facilitate a secure and lasting coupling of the distal anchor to the surface of a body lumen. In some variations, the structure may be a grapple, as described herein. In some variations, an adhesive may be added to the proximal surface of the proximal-most member. The adhesive may be applied by a physician before inserting the proximal-most foldable member into the body lumen or applied after insertion. In other variations, the adhesive may be applied during a manufacturing process and covered with a liner. In some variations, the liner is removed by the physician prior to insertion. In other variations, the liner is configured to dissolve upon contact with bodily fluid or after a force is applied to the distal anchor. The adhesive may initially strengthen the bond of the proximal-most foldable member to the tissue and then gradually degrade in strength as fistula tract healing occurs or after fistula tract healing. Depending on the variation, the adhesive may create a fluid impermeable seal for at least 7, 14, 21, 28, 35, 60 or any other number of days. The structure for a secure and lasting coupling may also comprise microneedles, such as hooks and/or barbs. The microneedles may be distributed throughout the proximal surface of the proximal-most member, but may also be distributed at predetermined locations. In some variations, the microneedles are distributed along a perimeter of the proximal surface, but in other variations the microneedles may be distributed at a position where contact is anticipated, such as the inner sealing regions described herein.

In some variations, a drug-eluting or therapeutic agent may be added to the distal anchor or the suture associated therewith. The drug-eluting or therapeutic agent may include healing factors, antibiotics, or other healing agents, for example. In some variations, the drug-eluting agent is coated on a foldable member or a suture. In other variations, the therapeutic agent is impregnated within a foldable member or a suture and may be configured for latent release.

In some variations, one or more of the foldable members or the suture may comprise a radio-opaque material or radio-opaque markers. In this way, the distal anchor or suture can be viewed in vivo by using an X-ray, CT scanner, or similar imaging devices.

FIGS. **18** to **24** depict cross-sectional views of exemplary topographical features for coupling adjacent foldable members. FIG. **18** depicts a cross-sectional view of distal anchor **1800** comprising foldable members **1802**, **1804**, **1806**, and **1808** in the deployed configuration. The cross-sectional profile of each foldable member can be characterized as having two dimensions, a width dimension (horizontal dimension as viewed in FIG. **18**) and a height dimension (vertical dimension as viewed in FIG. **18**). The foldable members are configured to generally orient the width dimension of the distal anchor **1800** in parallel with the surface of a body lumen when the distal anchor is in the restrained configuration. Each of the foldable members **1802**, **1804**, **1806**, and **1808** include topographical features configured to restrain relative movement of the foldable members in a direction parallel to the width of the foldable member. In this way, distal anchor **1800** may be rigidly coupled to the surface of the body lumen.

A proximal surface of each of the distal-most foldable member **1802**, first inner foldable member **1804**, and second inner foldable member **1806** is contoured to receive a distal surface of the first inner foldable member **1804**, second inner foldable member **1806**, and proximal-most foldable member **1808**, respectively. The surface contours of each of the foldable members serve to relatively restrain the foldable members in the width dimension. Because the cross-sectional view shown in FIG. **18** is at least partially revolved about an axis generally oriented in the height dimension, the surface contours of each of the foldable members serve to relatively restrain the foldable members in a plane orthogonal to the height dimension. Further, because a suture restrains the foldable members in the height dimension, the foldable members of the distal anchor **1800** is relatively restrained in three orthogonal dimensions, thereby securely holding the distal anchor in position on the surface of a body lumen at the distal opening of a fistula tract.

Proximal-most foldable member **1808** may be generally described as having an inner region **1810** and an outer region **1812** on its distal surface. Inner region **1810** may be defined as a generally smooth surface, such as a surface with a constant radius of curvature. Outer region **1812** may be defined as beginning at a point at which the constant radius of curvature ends—such as the angular region **1818** identified in FIG. **18**—and continuing until the peripheral edge of foldable member **1808**. Outer region **1812** may be a distal protrusion **1814** and inner region **1810** may be a recess, such as depicted in FIG. **18**. In other variations, an inner region is a distal protrusion and an outer region is a recess. The proximal surface of the foldable member adjacent to the proximal-most foldable member may be contoured to relatively restrain the adjacent foldable member. For example, second inner foldable member **1806** comprises a proximally protruding inner region and a recessed outer region, as depicted in FIG. **18**.

Distal protrusion **1814** of proximal-most foldable member **1808** restrains the second inner foldable member **1806** in the width dimension. Protrusion **1814** may be characterized by angular region **1816**, angular region **1818**, angular region **1820**, and the length of the sides **1822** and **1824** connecting angular region **1816** to angular region **1820** and angular region **1820** to angular region **1818**, respectively. Angular region **1816** may be characterized as the angle between a proximal surface of the proximal-most foldable member **1808** and the side **1822** of the proximal-most foldable member **1808**. In some variations, this angle may be any angle between 0 and 90 degrees, including 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, and 90°, or any range between any two of the above angles. Angular region **1818** may be characterized as the angle between the side **1824** of the proximal-most foldable member **1808** and the surface of the inner region **1810** of the proximal-most foldable member **1808**. In some variations, this angle may be any angle between 180 and 270 degrees, including 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, and 270°, or any range between any two of the above angles. In some further variations, angular region **1818** may include an angle greater than 270 degrees to provide a

"snap-fit" with an opposing surface of an adjacent foldable member. Angular region **1820** may be characterized as the angle between the side **1822** of the proximal-most foldable member **1808** and the side **1824** of the proximal-most foldable member **1808**. In some variations, this angle may be any angle between 0 and 180 degrees, including 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. Although angles **1816**, **1818**, and **1820** are depicted in FIG. **18** as sharp corners, other variations may include filleted or rounded angles. Sides **1822** and **1824** may be linear or non-linear. For example, side **1822** may be curved where side **1824** may be flat. In other variations, side **1822** may be flat and side **1824** may be curved. In yet other variations, sides **1822** and **1824** may be both curved or both flat. Sides **1822** and **1824** may be characterized as a percentage of the width of the proximal-most foldable member **1808** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

The relative widths of the inner regions and outer regions may be varied. In some variations, the width of the inner region is characterized as a percentage of the width of the outer region and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the width of the outer region is characterized as a percentage of the width of the inner region and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Proximal-most folding member **1808** is depicted as comprising an inner region which is relatively thin with respect to the total thickness of the distal anchor **1800** in the constrained configuration. In some variations, the thickness of the inner region is characterized as a percentage of the thickness of the distal anchor **1800** in the constrained configuration and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Proximal-most foldable member **1808** is illustrated as comprising a generally concave proximal surface with a constant radius of curvature. In other variations, the proximal surface of proximal-most foldable member **1808** has a non-constant radius of curvature. In yet other, variations the proximal surface of proximal-most foldable member **1808** comprises any of the surface geometries described herein. In some variations, the proximal surface of proximal-most foldable member **1808** is contoured to improve alignment with a non-planar surface of a body lumen.

In some variations, the cross-sectional profile of the foldable members illustrated in FIG. **18** is rotated 180 degrees to generate the three-dimensional geometry of the foldable members. That is, the cross-sectional profile illustrated in FIG. **18** may be representative of any cross-sectional profile taken through a center point of the foldable members. In other variations, the profile is not rotated 180 degrees, that is, the foldable member may not comprise the same cross-sectional profile taken through a center point of the foldable member at every angle. For example, the cross-sectional profile illustrated in FIG. **18** may be repeated for a first range of degrees and then a different cross-sectional profile repeated for a second range of degrees. For example, the cross-sectional profile for the first range may be that depicted in FIG. **18** where the cross-sectional profile for the second range may be generally smooth. This patterning may better facilitate folding of the foldable members, while still relatively restraining the foldable members. In some variations, the first range is larger than the second range.

The second inner foldable member **1806** may comprise a proximal surface that is contoured to align exactly with the contours of the distal surface of proximal-most foldable member **1808**. In some variations, the surfaces do not align exactly and may be contoured only as is necessary to provide a predetermined limit on relative movement between the foldable members in the transverse direction. As depicted in FIG. **18**, the proximal surface of the second foldable member **1806** has a similar geometry to the proximal surface of the proximal-most foldable member **1808**. In other variations, the proximal surface of the second inner foldable member **1806** has a dissimilar geometry to the proximal surface of the proximal-most foldable member **1808**. Further, although the inner and outer regions of the second foldable member **1806** have similar widths to the inner and outer regions of the proximal-most foldable member, other variations may have dissimilar widths. Likewise, although the angles on the distal surface of the second inner foldable member **1806** are similar to the angles on the distal surface of the proximal-most foldable member **1808**, other variations have dissimilar angles as those on the distal surface of the proximal-most foldable member **1808**. Any angular features on first inner foldable member **1804** may take any of the angles described above with respect to proximal-most foldable member **1808**. Similarly, any inner and outer regions of inner foldable member may take any of the relative thickness described above with respect to proximal-most foldable member **1808**.

Additional inner foldable members may take similar structures and provide similar functions as those described above with respect to second inner foldable member **1806**. For example, first inner foldable member **1804** may comprise a proximal surface configured to align exactly with the contours of the distal surface of second inner foldable member **1806**, but other variations may not align the opposing surfaces exactly. Any angular features on second inner foldable member **1806** may take any of the angles described above with respect to proximal-most foldable member **1808**. Similarly, any inner and outer regions of first inner foldable member **1804** may take any of the relative widths described above with respect to proximal-most foldable member **1808**.

Similarly, the proximal surface of distal-most foldable member **1802** may take similar structures and provide similar functions as those described above with respect to the proximal-most foldable member **1808** and the inner foldable members **1804** and **1806**. Any angular features on distal-most foldable member **1802** may take any of the angles described above with respect to the inner foldable member **1804** and **1806**. Similarly, any inner and outer regions of distal-most foldable member **1802** may take any of the relative thickness described above with respect to proximal-most foldable member **1808**.

Distal-most foldable member **1802** may be concave on its distal surface, as depicted in FIG. **18**. In some variations, the distal surface of distal-most foldable member **1802** is not concave. In particular, the distal surface of the distal-most foldable member is not constrained by an interaction with the surface of a distally adjacent foldable member. Accordingly, the distal surface of distal-most foldable member **1802** may be smooth to prevent any lodging of external elements, such as partially digested foot particles. In some variations, the distal surface of distal-most foldable member **1802** may take a form that facilitates folding of foldable member prior to deployment. In some variations, the distal surface of distal-most foldable member **1802** comprises a suture attachment

structure. In further variations, the suture attachment structure may include reinforcement structure **1826**. Reinforcing structure **1826** may be a wire mesh embedded within distal-most foldable member **1802** and configured to distribute the force resulting from tensioning the suture across all or some of distal-most foldable member **1802**, thereby reducing the risk of rupturing the foldable member. In other variations, the reinforcing structure might include a button-shaped suture attachment structure, wherein the expanded areas of the button-shaped suture attachment structure serves to distribute the force over a wider area.

FIG. **19** depicts a cross-sectional view of distal anchor **1900** comprising distal-most foldable member **1902**, first inner foldable member **1904**, second inner foldable member **1906**, and proximal-most foldable member **1908** in the deployed configuration. Distal anchor **1900** includes additional distal protrusions on the foldable members for further restraining the relative movement of the foldable members. Proximal-most foldable member **1908** comprises a first inner region **1910**, a first distal protrusion **1912**, a second inner region **1914**, and an outer region **1916**. Outer region **1916** may comprise similar features and structures to outer region **1814** described above with respect to distal anchor **1800**. Similarly, the first inner region **1910** may comprises similar features to inner region **1810** described above with respect to distal anchor **1800**. First distal protrusion **1912** may limit relative movement of second inner foldable member **1906** relative to proximal-most foldable member **1908**.

First distal protrusion **1912** of proximal-most foldable member **1908** restrains the second inner foldable member **1906** in the width dimension. Protrusion **1914** may be characterized by angular region **1918**, angular region **1920**, angular region **1922**, and the length of the sides **1924** and **1926** joining angular region **1918** to angular region **1920** and angular region **1920** to angular region **1922**, respectively. Angular region **1918** may be characterized as the angle between the second inner region **1914** and the side **1924**. In some variations, this angle may be any angle between 180 and 270 degrees, including 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, and 270°, or any range between any two of the above angles. In some further variations, angular region **1918** may include an angle greater than 270 degrees to provide a "snap-fit" with an opposing surface of an adjacent foldable member. Angular region **1920** may be characterized as the angle between the side **1924** and the side **1926**. In some variations, this angle may be any angle between 0 and 180 degrees, including 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. Angular region **1922** may be characterized as the angle between the first inner region **1910** and the side **1926**. In some variations, this angle may be any angle between 180 and 270 degrees, including 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, and 270°, or any range between any two of the above angles. In some further variations, angular region **1922** may include an angle greater than 270 degrees to provide a "snap-fit" with an opposing surface of an adjacent foldable member. Although angles **1918**, **1920**, and **1922** are depicted in FIG. **19** as sharp corners, other variations may include filleted or rounded angles. Sides **1924** and **1926** may be linear or non-linear. For example, side **1924** may be curved where side **1926** may be flat. In other variations, side **1924** may be flat and side **1926** may be curved. In yet other variations, sides **1924** and **1926** may be both curved or both flat. The length of each of sides **1924** and **1926** may be characterized as a percentage of the width of the proximal-most foldable member **1908** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

The relative widths of first inner region **1910**, first distal protrusion **1912**, second inner region **1914**, and outer region **1916** may be varied. In some variations, the widths of first inner region **1910**, first distal protrusion **1912**, and second inner region **1914** may be characterized as percentages of the width of outer region **1916** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the widths of first inner region **1910**, first distal protrusion **1912**, and outer region **1916** may be characterized as percentages of the width of second inner region **1914** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the widths of first inner region **1910**, second inner region **1914**, and outer region **1916** may be characterized as percentages of the width of first distal protrusion **1912** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the widths of first distal protrusion **1912**, second inner region **1914**, and outer region **1916** may be characterized as percentages of the width of first inner region **1910** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Second inner foldable member **1906** may comprise a recess **1928** on its proximal surface corresponding to the first distal protrusion **1912** of proximal-most foldable member **1908**. Recess **1928** may be defined by the length of the side surfaces and the angles created where the sides meet each other and where the sides meet the proximal surface of second inner foldable member. The lengths of the side surfaces may be characterized as a percentage of the diameter of the proximal-most foldable member **1908** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The angle may correspond to the angles of the distal protrusion **1912** on proximal-most foldable member **1908**.

First inner foldable member **1904** may comprise a recess on its proximal surface corresponding to a distal protrusion on second foldable member **1906**. The recess may be defined by the length of the side surfaces and the angles created where the sides meet each other and where the sides meet the proximal surface of second inner foldable member. The lengths of the side surfaces may be characterized as a percentage of the width of the proximal-most foldable member **1908** and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The angle may correspond to the angles of the distal protrusion on second inner foldable member **1906**.

Distal-most foldable member **1902** may share similar geometries and functions as distal-most foldable member **1802**.

Although FIGS. **18** and **19** illustrate one and two distal protrusions, respectively, on a distal surface of the proximal-most foldable member, other variations may have 3, 4, 5, or any number of protrusions. Further, although FIGS. **18** and **19** illustrate a distal protrusion on the perimeters of the proximal-most foldable member, first inner foldable member, and second inner foldable member, other variations may have a distal recess on the perimeter of any of the foldable members.

FIGS. **20**A to **20**C depict various protrusions and recesses configured for coupling adjacent foldable members. FIG. **20**A depicts a cross-sectional view of protrusion **2002** of a proximal foldable member configured to be coupled to a recess **2010** of a distal foldable member adjacent to the proximal foldable member. As can be seen in FIG. **20**A, protrusion **2002** comprises two angled sides **2004** and **2006** connected by a rounded apex **2008**. Recess **2010** comprises an inner proximal surface **2012** and an outer proximal surface **2014** connected by a fillet **2016**. The distal foldable member further comprises a distal surface including inner distal surface **2018** and outer distal surface **2020**. Inner distal surface **2020** may be oriented approximately in parallel to a distal surface of the proximal foldable member. In this way, the distal foldable member provides more material behind the face at which the recess **2010** and protrusion **2002** are forced together. That is, as the distal foldable member is restrained, the inner proximal surface **2012** of the distal foldable member is forced against the side **2004** of the proximal foldable member. Including additional material behind this point may provide additional support to the distal foldable member when the two foldable members are forced together. By contrast, there is less force exerted on the outer proximal surface **2014**. Accordingly, outer distal surface **2020** may be generally parallel to the side **2006**, resulting in a thinner outer region of the distal foldable member. This may facilitate folding the foldable member prior to insertion or may provide a reduction in manufacturing costs.

FIG. **20**B depicts a cross-sectional view of protrusion **2030** of a proximal foldable member configured to be coupled to a recess **2032** of a thin inner foldable member adjacent to the proximal foldable member, where the recess **2032** is further configured to be coupled to a recess **2034** of a distal foldable member. Introducing a thin inner foldable member between the distal and proximal foldable member may further distribute the pressure on the foldable members when in the restrained configuration. In addition, inner foldable member may comprise an adhesive to strengthen the coupling between the proximal and distal foldable members.

FIG. **20**C depicts a cross-sectional view of protrusion **2040** of a proximal foldable member configured to be coupled to a recess **2042** of a distal foldable member. Recess **2042** includes a cavity **2044** which may facilitate coupling of the distal and proximal foldable members without deforming the proximal-most foldable member. More specifically, as the distal foldable member is restrained, the recess **2042** slides laterally on the protrusion **2040** so that the cavity **2044** moves to the other side of protrusion **2040**. In this way, no additional forces may be exerted on the protrusion **2040** in the lateral direction due to restraining the distal foldable member.

FIG. **21** depicts a cross-sectional view of a portion **2100** of a distal anchor, comprising proximal-most foldable member **2102** and first inner foldable member **2104**. Proximal-most foldable member **2102** has distal protrusion **2106** in its outer region. Distal protrusion **2106** may comprise the geometry of any of the protrusions described herein. Inner region **2108** of proximal-most foldable member **2102** comprises teeth **2110** configured to restrain relative movement of the first inner foldable member. The proximal surface of the first inner foldable member may also comprise teeth **2112** configured to engage with the teeth **2108** of the proximal-most foldable member. The distal surface of the first inner foldable member **2104** may also comprise teeth **2114** configured to engage with a proximal surface of an adjacent foldable member (not shown).

In some variations, teeth configured to restrain movement may take the form of a series of peaks and troughs. In some variations, the peaks and troughs may be symmetrical. In other variations, the peaks and troughs may not be symmetrical. In some variations, the peaks and troughs may repeat at constant distances. In other variations, the peaks and troughs may be distributed unevenly throughout the surface of the foldable member. In some variations, the peaks and troughs are rounded. In others, some or all of the peaks and troughs have pointed edges. In some variations, an opposing surface of an adjacent foldable member may have a recess configured to receive the teeth. In other variations, the opposing surface of the adjacent foldable member does not include a recess for one or more of the teeth. In some variations, each surface of a foldable member that opposes a surface of an adjacent foldable member has teeth. In other variations, one or more of the foldable members of a distal anchor does not include teeth. In some variations, the teeth protrude the same distance from the surface of the foldable member. In other variations, one or more teeth protrude at a different distance from the surface of the foldable member. In some variations, the distance the teeth protrude from the surface of the foldable member may be characterized as a percentage of the thickness of the foldable member without the teeth and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the foldable member without the teeth may be characterized as a percentage of the distance the teeth protrude from the surface of the foldable member and may sometimes be about 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

FIG. **22** depicts a cross-sectional view of a portion **2200** of a distal anchor comprising teeth between adjacent foldable members **2202** and **2204**. Proximal-most foldable member **2202** may have some features which are similar to proximal-most foldable member **2102** described above with respect to FIG. **21**. Proximal-most foldable member **2202** may be thicker than proximal-most foldable member **2102**, resulting in a wider outer region **2206**. First inner foldable member **2204** may have some features which are similar to first inner foldable member **2104** described above with respect to FIG. **21**. Proximal-most foldable member **2202** and first inner foldable member **2204** may comprise central regions **2208** and **2210**, respectively, without teeth. An aperture may be positioned in central regions **2208** and **2210** for receiving a suture.

FIG. **23**A depicts a cross-sectional view of a set **2300** of teeth configured for coupling adjacent foldable members. Each tooth may comprise a first angular region **2304**, a first side **2306**, a second angular region **2308**, a second side **2310**, a third angular region **2312**, a third side **2314**, and a fourth angular region **2316**. First angular region **2304** may be characterized by the angle created by the surface of the foldable member **2302** and the first side **2306**, where the angle may sometimes be 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, and 270°, or any range between any two of the above angles. First side **2306** may be characterized as a percentage of the thickness of the foldable member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Second angular region **2308** may be characterized by the angle created by the first side **2306** and the second side **2310**, where the angle may sometimes be 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, 270°, 280°, 290°, 300°, 310°, 320°, 330°, 340°, 350°, and 360°, or any range between any two of the above angles. Second side **2310** may be characterized as a percentage of the thickness of the foldable member and may sometimes be 5%, 10%, 20%,

30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Third angular region **2312** may be characterized by the angle created by the second side **2310** and the third side **2314**, where the angle may sometimes be 270°, 280°, 290°, 300°, 310°, 320°, 330°, 340°, 350°, and 360°. Third side **2314** may be characterized as a percentage of the thickness of the foldable member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Fourth angular region **2304** may be characterized by the angle created by the surface of the foldable member **2302** and the third side **2314**, where the angle may sometimes be 270°, 280°, 290°, 300°, 310°, 320°, 330°, 340°, 350°, and 360°, or any range between any two of the above angles.

FIG. **23**B depicts a cross-sectional view of a set **2330** of teeth configured for coupling adjacent foldable members. Each tooth may comprise a first angular region **2334**, a first side **2336**, a second angular region **2338**, a second side **2340**, and a third angular region **2332**. First angular region **2334** may be characterized by the angle created by the surface of the foldable member **2332** and the first side **2336**, where the angle may sometimes be 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, and 270°, or any range between any two of the above angles. First side **2336** may be curved, wherein the length of the curve is characterized as a percentage of the thickness of the foldable member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Second angular region **2338** may be characterized by the angle created by the first side **2336** and the second side **2340**, where the angle may sometimes be 180°, 190°, 200°, 210°, 220°, 230°, 240°, 250°, 260°, 270°, 280°, 290°, 300°, 310°, 320°, 330°, 340°, 350°, and 360°, or any range between any two of the above angles. Second side **2340** may be characterized as a percentage of the thickness of the foldable member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages Third angular region **2342** may be characterized by the angle created by the surface of the foldable member **2332** and the third side **2340**, where the angle may sometimes be 270°, 280°, 290°, 300°, 310°, 320°, 330°, 340°, 350°, and 360°, or any range between any two of the above angles.

FIG. **23**C shows a cross-sectional view of pair **2350** of foldable members, first foldable member **2352** and second foldable member **2354**. First foldable member **2352** may comprise recesses **2362** configured to receive teeth **2360** on second foldable member **2354**. As can be seen in FIG. **23**C, the teeth and recesses are symmetrical about a center point of each foldable member. This may facilitate an annular rib on the foldable member when viewed in three-dimensions, that is, when the cross-section depicted in FIG. **23**C is revolved 180 degrees. In other variations, the teeth may not be symmetrical about a center point of each foldable member.

FIG. **24** depicts a cross-sectional view of foldable member **2400** which comprises teeth **2402** and **2404**. Teeth **2402** and **2404** may include a surface of relatively large curvature, thereby facilitating a snap-fit when foldable member **2400** engages recesses in an adjacent foldable member. Teeth **2402** and **2404** may be configured to move transversely within the recess of the adjacent foldable member as the pair of foldable members are forced together.

FIG. **25** illustrates a cut-away, exploded view of a distal anchor **2500** comprising a distal-most foldable member **2502**, an inner foldable member **2504**, and a proximal-most foldable member **2506**. Inner foldable member **2504** and proximal-most foldable member **2506** comprise recesses **2522** and **2532**, respectively, configured to receive the distally adjacent foldable member. The design of distal anchor **2500** may serve to relatively restrain the foldable members while sill reducing manufacturing costs. Proximal-most foldable member **2530** may further comprise structure on its proximal surface to enable the distal anchor **2500** to better couple to a surface of a body lumen at the distal opening of a fistula tract.

Distal-most foldable member **2502** comprises generally concave distal and proximal surfaces. As illustrated in FIG. **25**, the distal surface of distal-most foldable member **2502** has a greater curvature than the proximal surface, that is, the distal surface of distal-most foldable member **2502** has a smaller radius of curvature than the proximal surface. The greater curvature of the distal surface results in a thicker central region, which may provide additional structural support when a suture (not shown) is attached to a suture attachment structure (not shown) on the distal-most foldable member **2502**. In some variations, the radius of curvature of the distal surface may be characterized as a percentage of the radius of curvature of the proximal surface and sometimes may be 75%, 80%, 85%, 90%, 95%, 100%, or any percentage range between any two of the above percentages. In other variations, the proximal surface of the distal-most foldable member **2502** comprises a greater curvature than the distal surface that is, the proximal surface of distal-most foldable member **2502** has a smaller radius of curvature than the distal surface. In some variations, the radius of curvature of the proximal surface may be characterized as a percentage of the radius of curvature of the distal surface and sometimes may be 75%, 80%, 85%, 90%, 95%, 100%, or any percentage range between any two of the above percentages. Distal-most foldable member **2502** also comprises a distal angular region **2508**, a perimeter surface **2510**, and a proximal angular region **2512**. Distal angular region **2508**, perimeter surface **2510**, and proximal angular region **2512** may be configured to mate distal-most foldable member **2502** with a recess in inner foldable member **2504**. Distal angular region **2508** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the diameter of the distal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle may sometimes be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In other variations, distal angular region **2508** may be a pointed corner created by the distal surface of distal-most foldable member **2502** and the perimeter surface **2510**. In some variations, the angle of the pointed corner may be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In some variations, perimeter surface **2510** may comprise a length characterized as a percentage of the diameter of the distal-most foldable member, and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, or any percentage range between any two of the above percentages. In some variations, proximal angular region **2512** may be a pointed corner created by the proximal surface of distal-most foldable member **2502** and the perimeter surface **2510**. In some variations, the angle of the pointed corner may be 0°, 30°, 60°, 90°, 120°, 150°, 180°, or any range between any two of the above angles.

Inner foldable member **2504** comprises a proximal surface and a distal surface. As with distal-most foldable member **2502**, the proximal surface may have a different curvature than the distal surface. The distal surface comprises an

elevated region **2520** and a recessed region **2522**. Elevated region **2520** may include a distal angular region **2514**, a perimeter surface **2516**, and a proximal angular region **2518**. Distal angular region **2514**, perimeter surface **2516**, and proximal angular region **2518** may comprise any of the geometries discussed above with respect to distal angular region **2508**, perimeter surface **2510**, and proximal angular region **2512**. Recessed region **2522** may be configured to mate inner foldable member **2504** with the proximal surface of distal-most foldable member **2502**. Recessed region **2522** may comprise a distal angular region **2524**, an interior surface **2526**, and a proximal angular region **2528**. Distal angular region **2524**, interior surface **2526**, and proximal angular region **2528** may be configured to mate recess **2522** of inner foldable member **2504** with distal-most foldable member **2502**. Distal angular region **2524** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the diameter of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle may sometimes be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In other variations, distal angular region **2524** may be a pointed corner created by the surface of elevation **2520** and the interior surface **2526**. In some variations, the angle of the pointed corner may be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In some variations, interior surface **2526** may comprise a length characterized as a percentage of the diameter of the inner foldable member, and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, or any percentage range between any two of the above percentages. In some variations, proximal angular region **2528** may be a pointed corner created by the surface of recess **2522** and the interior surface **2526**. In some variations, the angle of the pointed corner may be 0°, 10°, 20°, 30°, 60°, 90°, 120°, 150°, 180°, or any range between any two of the above angles.

Proximal-most foldable member **2506** comprises a proximal surface and a distal surface. The distal surface comprises a sloped region **2530** and a recessed region **2532**. Recessed region **2532** may be configured to mate inner foldable member **2504** with the distal surface of proximal-most foldable member **2506**. Recessed region **2532** may comprise a distal angular region **2534**, an interior surface **2536**, and a proximal angular region **2538**. Distal angular region **2534** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the diameter of the proximal-most foldable member, and may sometimes be 55%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle may sometimes be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles. In other variations, distal angular region **2534** may be a pointed corner created by the surface of sloped region **2530** and the interior surface **2536**. In some variations, the angle of the pointed corner may be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In some variations, interior surface **2536** may comprise a length characterized as a percentage of the diameter of the inner foldable member, and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, or any percentage range between any two of the above percentages. In some variations, proximal angular region **2538** may be a pointed corner created by the surface of recess **2532** and the interior surface **2536**. In some variations, the angle of the pointed corner may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles.

The proximal surface of proximal-most foldable member **2506** may be configured to provide additional support. The proximal surface of proximal-most foldable member may include a recess **2544** and a proximal protrusion **2546**. Both recess **2544** and proximal protrusion **2546** may be defined by an arc of a length and an angle. In some variations, the length of the arc is characterized as a percentage of the diameter of the inner foldable member, and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle may sometimes be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles. Proximal protrusion **2546** may comprise an inner sealing region to prevent-ingress of fistula material to the body lumen. Angular region **2542** may comprise an outer edge region of the proximal-most foldable member. In some variations, the outer edge region is oriented at an acute angle to the inner sealing region. In some embodiments, the position of the proximal protrusion may be characterized as a percentage of the diameter of the proximal-most foldable member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Although distal anchor **2500** is illustrated with three foldable members, other variations may include four or more foldable members. Additional foldable members may comprise additional inner foldable members configured to mate to adjacent foldable members. In addition, although the foldable members are illustrated as having an overall curved form, in some variations the foldable members may have an overall planar form. Moreover, any of the overall shapes described herein may be employed. The distal-most and inner foldable members are depicted with a smooth proximal surface, but some variations may include topographical features configured to further restrain relative movement between the foldable members, such as those described herein. In addition, although a suture, a suture attachment structure, and apertures for threading a suture are not illustrated in FIG. **25**, some variations include all or some of a suture, a suture attachment structure, and apertures for threading a suture, such as those described herein.

FIG. **26** illustrates a cut-away, exploded view of a distal anchor **2600** comprising distal-most foldable member **2602**, first inner foldable member **2604**, second inner foldable member **2606**, and proximal-most foldable member **2608**. Foldable members **2602**, **2604**, and **2606**, and **2610** are relatively less curved than the foldable members of distal anchor **2500**. Second inner foldable member **2606** and proximal-most foldable member **2608** comprise annular ribs **2620** and **2630**, respectively. Annular ribs **2620** and **2630** may serve to relatively restrain the foldable members of distal anchor **2600** is in the deployed configuration. The distal surface of each of first inner foldable member **2604**, second inner foldable member **2606**, and proximal-most foldable member **2608** may comprise an outer distally protruding region and an inner recess. As can be seen in FIG. **26**, the width of the outer regions may vary. In other variations, the widths of the outer regions are the same.

As depicted in FIG. **26**, annular rib **2620** may be aligned with annular rib **2630**, and annular rib **2630** may be aligned

with a side surface of a recess in first inner foldable member **2604**. In some variations, the annular ribs are not aligned with features on the distal face of the adjacent foldable member. The positioning of the annular ribs on each foldable member may be characterized by a diameter that is a percentage of the overall diameter of the distal anchor **2600**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The annular ribs may also comprise a width from the bottom of the slope of one face to the bottom of the slope of the other face, that is, a width of the base of the rib. The widths of the annular ribs may be characterized as a percentage of the overall diameter of the distal anchor **2600**, and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, or any percentage range between any two of the above percentages. Although annular rib **2630** is illustrated as comprising a pointed apex, other variations may include a rounded or flat apex, such as any of the protrusion geometries discussed herein. Similarly, annular rib **2620** is illustrated as comprising a flat apex, but other variations may include a rounded or pointed apex, such as any of the protrusion geometries discussed herein.

Distal-most foldable member **2602** comprises a generally planar proximal surface and a curved distal surface, with a side surface connecting the proximal and distal surfaces. The side surface of distal-most foldable member **2602** may be oriented at an acute angle to the height dimension, wherein the angle may sometimes be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. The thickness of distal-most foldable member **2602** may be characterized as a percentage of the overall thickness of the distal anchor **2600** in the deployed configuration, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The diameter of distal-most foldable member **2602** may be characterized as a percentage of the diameter of proximal-most foldable member **2608**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

First inner foldable member **2604** may comprise a protruding outer region and a recess on its distal face. First inner foldable member **2604** may also comprise a recess on its proximal face, which may be aligned with an annular rib on second inner foldable member **2606**. The protrusions and recess of first inner foldable member **2604** may comprise any of the protrusion and recess geometries described herein.

Second inner foldable member **2606** may comprise a protruding outer region, a first recess, an annular rib, and a second recess on its distal face. The relative size and positions of the first and second recesses may be determined by the positioning and size of the annular rib. Second inner foldable member **2606** may comprise a recess on its proximal face. The protrusions and recess of second inner foldable member **2606** may comprise any of the protrusion and recess geometries described herein.

Proximal-most foldable member **2608** may comprise a protruding outer region, a first recess, an annular rib, and a second recess on its distal face. The relative size and positions of the first and second recesses may be determined by the positioning and size of the annular rib. Proximal-most foldable member **2608** may comprise a smooth proximal face. The protrusions and recess of proximal-most foldable member **2608** may comprise any of the protrusion and recess geometries described herein.

FIG. **27** depicts a cut-away, exploded view of a distal anchor **2700** comprising distal-most foldable member **2702**, first inner foldable member **2704**, second inner foldable member **2706**, and proximal-most foldable member **2708**. Foldable members **2702-2708** may have less curvature than the foldable members described above with respect to distal anchor **2500**. In addition, inner foldable members **2704** and **2706** may have recesses configured to receive a proximal surface of the distally adjacent foldable member and protruding outer regions configured to relatively restrain the distally adjacent foldable members, similar to the inner foldable members in distal anchors **2500** and **2600**. The recesses and protruding outer regions of inner foldable members **2704** and **2706** may take any of the geometries described above with respect to distal anchors **2704** and **2706**.

Proximal-most foldable member comprises annular ribs **2710**, **2712**, **2714**, **2718**, and **2720**. Annular ribs **2710**, **2712**, **2714**, **2718**, and **2720** may provide a separation between the proximal-most foldable member **2708** and the second inner foldable member **2706** while also providing a resistance to relative motion between the two adjacent foldable members. Although six annular ribs are shown in FIG. **27**, other variations may include other numbers of annular ribs, including 2, 3, 4, 5, 7, 8, 9 and 10 annular ribs. Further, although the annular ribs in FIG. **27** are concentric, in other variations the annular ribs are not concentric. Further, the annular ribs in FIG. **27** are separated by an equal distance, but in other variations, the annular ribs may be separated by different distances. The geometry of each annular rib may be characterized by an inner surface that is oriented approximately in parallel to the height dimension and an outer surface that is oriented at an angle to the height dimension, wherein the angle may sometimes be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, and 90°, or any range between any two of the above angles. In some variations, the height of the inner surface of each rib may be characterized as a percentage of the thickness of the proximal-most member without the ribs and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In other variations, the thickness of the proximal-most member without the ribs may be characterized as a percentage of the height of the inner surface of each rib and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

FIG. **28** depicts a cross-sectional exploded view of a distal anchor **2800** comprising distal-most foldable member **2802**, inner foldable member **2804**, and proximal-most foldable member **2806**. Foldable members **2802**, **2804**, and **2806** may have greater curvature than the foldable members of distal anchors **2500**, **2600**, and **2700**. In addition, a proximal protrusion on inner foldable member **2804** and proximal-most foldable member **2806** may protrude further than the proximal protrusions of distal anchors **2500**, **2600**, and **2700**. Inner foldable member **2804** also include a recess at the base of the proximal protrusion to improve mating to the distally adjacent foldable member. Further, the distal surface of distal-most foldable member **2802** may be tapered at its perimeter to improve mating with proximal-most foldable member **2802**.

Distal-most foldable member **2802** includes an outer region on its distal surface which may be tapered to improve mating. The outer region includes a distal angular region **2808**, a planar surface **2810**, and a proximal angular region **2812**. Distal angular region **2808** may create an obtuse angle where the distal surface of distal-most foldable member **2802** and planar surface **2810** meet. In some variations, the angle may sometimes be 90°, 100°, 110°, 120°, 130°, 140°, 150°,

160°, 170°, and 180°, or any range between any two of the above angles. Proximal angular region **2812** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the distal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the distal-most foldable member is characterized as a percentage of the radius of proximal angular region **2812**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of proximal angular region **2812** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles. In some variations, the length of planar surface **2810** is characterized as a percentage of the thickness of the distal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the distal-most foldable member is characterized as a percentage of the length of planar surface **2810**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Inner foldable member **2804** includes an outer region on its distal surface which comprises a protrusion and a recess. The recess comprises a distal angular region **2814**, a first planar surface **2816**, a proximal angular region **2824**, and a second planar surface **2820**. Distal angular region **2814** may create an obtuse angle where the distal surface of inner foldable member **2804** and first planar surface **2816** meet. In some variations, the angle may sometimes be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°. In some variations, the length of first planar surface **2816** is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the length of first planar surface **2816**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Proximal angular region **2824** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the radius of proximal angular region **2824**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of proximal angular region **2824** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In some variations, the length of second planar surface **2820** is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the length of second planar surface **2820**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The protrusion on the outer region of inner foldable member **2804** comprises a distal angular region **2818**, a planar surface **2822**, and a proximal angular region **2826**. Distal angular region **2818** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the radius of distal angular region **2818**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of distal angular region **2818** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles. In some variations, the length of planar surface **2822** is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the length of planar surface **2822**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Proximal angular region **2820** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the inner foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the inner foldable member is characterized as a percentage of the radius of proximal angular region **2820**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of proximal angular region **2820** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles.

Proximal-most foldable member **2806** includes an outer region on its distal surface which comprises a protrusion and a recess. The recess comprises a distal angular region **2830**, a first planar surface **2832**, a proximal angular region **2836**, and a second planar surface **2834**. Distal angular region **2830** may create an obtuse angle where the distal surface of proximal-most foldable member **2806** and first planar surface **2832** meet. In some variations, the angle may sometimes be 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°, or any range between any two of the above angles. In some variations, the length of first planar surface **2832** is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the length of first planar surface **2832**, and may sometimes be 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%. Proximal angular region **2836** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%,

25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the radius of proximal angular region **2836**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of proximal angular region **2836** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, and 180°. In some variations, the length of second planar surface **2834** is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the length of second planar surface **2834**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. The protrusion on the outer region of proximal-most foldable member **2806** comprises a distal angular region **2842**, a planar surface **2840**, and a proximal angular region **2838**. Distal angular region **2842** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the radius of distal angular region **2842**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of distal angular region **2842** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles. In some variations, the length of planar surface **2840** is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the length of planar surface **2840**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Proximal angular region **2838** may be an arc with a radius and an angle. In some variations, the radius is characterized as a percentage of the thickness of the proximal-most foldable member, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the thickness of the proximal-most foldable member is characterized as a percentage of the radius of proximal angular region **2838**, and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In some variations, the angle of proximal angular region **2838** may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, 90°, 100°, 110°, 120°, 130°, 140°, 150°, 160°, 170°, 180°, or any range between any two of the above angles.

FIG. **29** depicts a cut-away, exploded view of a distal anchor **2900** comprising distal-most foldable member **2902**, first inner foldable member **2904**, second inner foldable member **2906**, and proximal-most foldable member **2908**. Distal-most foldable member **2902**, first inner foldable member **2904**, second inner foldable member **2906**, and proximal-most foldable member **2908** may have less curvature than the foldable members of distal anchor **2800**. Distal-most foldable member **2902** may a tapered outer region similar to the tapered outer region of distal-most foldable member **2802**. First inner foldable member **2904**, second inner foldable member **2906**, and proximal-most foldable member **2908** may have recesses and protrusions in outer regions similar to those described above with respect to distal anchor **2800**. The protrusion in the outer region of proximal-most foldable member **2908** may be located inward from the perimeter of proximal-most foldable member **2908**, leaving a relatively thin region **2930** at the outermost part of proximal-most foldable member **2908**. The position of the protrusion of the proximal-most foldable member may be characterized as a percentage of the diameter of proximal-most foldable member **2908**, and sometimes may be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Proximal-most foldable member **2908** may also include features on its proximal surface configured to engage the surface of a body lumen. These features may be similar in geometry to curves **2544** and **2546** of distal anchor **2500**. In addition, distal-most foldable member **2902**, first inner foldable member **2904**, second inner foldable member **2906**, and proximal-most foldable member **2908** may comprise annular ribs **2910**, **2912**, **2914**, **2916**, **2918**, **2920**, **2922**, and **2924** on their proximal and/or distal surfaces. These annular ribs may restrain relative movement of the foldable members when the foldable members are in the restrained configuration. Each annular rib has an associated annular rib on the opposing surface of the adjacent foldable member. As the foldable members are restrained by a suture (not shown), each pair of annular ribs are forced together, thereby limiting the relative movement between the adjacent foldable members. The opposing annular ribs may comprise parallel surfaces on their opposing faces. Annular ribs **2910**, **2912**, **2914**, **2916**, **2918**, **2920**, **2922**, and **2924** may comprise a similar geometry as the annular ribs described above with respect to distal anchor **2700**.

FIG. **30** depicts a cross-sectional view of a distal anchor **3000**, comprising distal-most foldable member **3002**, first inner foldable member **3004**, second inner foldable member **3006**, and proximal-most foldable member **3008**. Distal-most foldable member **3002**, first inner foldable member **3004**, and second inner foldable member **3006** may comprise similar geometries to distal-most foldable member **1802**, first inner foldable member **1804**, and second inner foldable member **1806** discussed above with respect to distal anchor **1800**. In some variations, as depicted in FIG. **30**, the distal-most foldable member **3002**, first inner foldable member **3004**, and second inner foldable member **3006** may be curved. Distal-most foldable member **3002**, first inner foldable member **3004**, and second inner foldable member **3006** may have less curvature than the foldable members of distal anchor **2900**. The proximal surface of proximal-most foldable member may be substantially planar. The distal surface of proximal-most foldable member **3008** may comprise an outer region with a protrusion **3012** similar to protrusion **2546** discussed above with respect to distal anchor **2500**. Proximal-most foldable member **3008** may also comprise a flat surface **3010** connecting the edge of the proximal-most foldable member to protrusion **3012**. The proximal surface of proximal-most member **3008** may also comprise grapples **3014**, **3016**, and **3018** configured to engage the surface of a body lumen and restrain the distal anchor **3000** with respect to the body lumen.

In some variations, one or more of grapples **3014**, **3016**, and **3018** may be omitted. In other variations, additional grapples are added.

FIG. **31** depicts a portion **3100** of a distal anchor comprising inner foldable member **3102** and proximal-most foldable member **3104**. Inner foldable member **3102** may comprise a geometry similar to any of the inner foldable members described herein. Proximal-most foldable member **3104** may comprise a distal protrusion **3106** and outer region **3108**. Distal protrusion **3106** may comprise a geometry similar to any of the protrusions described herein. Outer region **3108** may comprise a geometry similar to any of the outer regions of the proximal-most foldable members described herein. Proximal-most foldable member **3104** also comprises a moveable protrusion **3110** on its distal surface, a recess **3112** on its proximal surface, and a grapple **3114** on its proximal surface. Moveable protrusion **3110** and recess **3112** may be aligned to create a region of reduced thickness in proximal-most foldable member **3104**. Recess **3112** and grapple **3114** may be interconnected so that grapple **3114** enters and grips the tissue of a body lumen as inner foldable member **3102** connects with proximal-most foldable member **3004**. More specifically, as the proximal surface of inner foldable member **3102** engages with moveable protrusion **3110**, the protrusion is forced proximally, thereby forcing distal recess **3112** proximally. Distal recess **3112** and grapple **3114** may be integrally coupled so that grapple **3114** moves proximally and inwardly as distal recess **3112** moves proximally. In this way, the proximal motion of inner foldable member **3102** is translated to a proximal and inward motion of grapple **3114**, thereby facilitating entering and gripping of the tissue.

Protrusion **3110** is depicted as circular, but in some variations protrusion **3110** is non-circular. When circular, protrusion **3110** might be characterized as an arc with a radius that intersects the distal surface of an inner region of proximal-most foldable member **3104**. In some variations, the radius of the arc is described as a percentage of the diameter of the proximal-most foldable member and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, 30%, or any percentage range between any two of the above percentages. In some variations, the arc does not have a constant radius. In some variations, protrusion **3110** may be less resistant to movement than surrounding areas of the proximal-most foldable member **3104**. In this way, protrusion **3110** may be configured to move relative to the surrounding area of proximal-most foldable member. In some variations, the reduction in resistance to deformation is facilitated by a decrease in the thickness of the proximal-most foldable member **3104** in the area of the protrusion **3110**. In other areas, the density of the material is reduced in the area of the protrusion **3110**. Although FIG. **31** depicts proximal-most foldable member **3104** as comprising a single protrusion configured to move relative to the surrounding area, other variations may have any number of such protrusions, including 2, 3, 4, 5, 6, 7, 8, and 10 protrusion. Further, FIG. **31** illustrates a protrusion on the distal surface of proximal-most foldable member **3102**, but some variations may include a protrusion on the proximal surface of inner foldable member **3102** and a flat surface or protrusion on the distal surface of proximal-most foldable member **3104**.

Grapple **3114** is illustrated as being "fang" shaped, but in other embodiments grapple **3114** takes an alternative shape, such as a hook shape, that can puncture the surface of a body lumen. Grapple **3114** may comprise barbs oriented away from the direction of insertion, thereby preventing withdrawal of the fang after insertion. In some variations, the length of grapple **3114** is described as a percentage of the thickness of proximal-most foldable member **3104** from its distal-most point to its proximal-most point, and the percentage may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. In other variations, the thickness of proximal-most foldable member **3104** from its distal-most point to its proximal-most point is described as a percentage of the length of grapple **3114**, and the percentage may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

Although FIG. **31** illustrates protrusion **3110**, recess **3112**, and grapple **3114** positioned near an edge of foldable member **3104**, other variations may have the grapple positioned at any location on proximal-most foldable member **3104**. In some variations, the position of the protrusion **3110**, recess **3112**, and grapple **3114** is characterized as a percentage of the radius of the proximal-most member and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Further, although portion **3100** is described with an inner foldable member, a distal-most foldable member may replace inner foldable member **3102** without deviating from the scope of the disclosure.

FIG. **32** illustrates a delivery device **3200** configured to transport one or more foldable members through a fistula tract and into a body lumen. Delivery device **3200** may be configured to reduce the cross-sectional profile of the foldable members so that the foldable members can be inserted into elongate tubular member **3202** that has an internal diameter less than the diameter of the foldable members. Delivery device **3200** may also include a profile reduction member **3204** for reducing the cross-sectional profile of the foldable members to a width no more than the diameter of the elongate tubular member **3202**. Once the foldable members are fully inserted into the elongate tubular member **3202**, the tubular member may be passed through a fistula tract until the elongate tubular member is aligned with, or distal to, the distal opening of the fistula tract. The foldable members may then be pushed through the distal end of elongate tubular member **3202** or elongate tubular member **3202** may be withdrawn to deploy the foldable members in a body lumen.

The interior diameter of the elongate tubular member **3204** may be characterized as a percentage of the diameter of a proximal-most foldable member and may sometimes be 1%, 2%, 3%, 4%, 5%, 10%, 15%, 20%, 25%, or any percentage range between any two of the above percentages. In some variations, profile reduction member **3204** is integrally connected to elongate tubular member **3202** and in other variations it is configured to removably couple to the tubular member. In some variations, the size and shape of a profile reduction section may be configured for a specific foldable member. For example, a distal-most foldable member may require a different profile reduction section than a larger proximal-most foldable member.

FIG. **32** depicts a conical profile reduction member **3204**. In some variations, the foldable member may be pushed through the conical profile reduction member by a rod. The rod may engage with the foldable member in the large dimension or the smaller dimension. For example, a rod may be used to push a foldable member on its proximal surface so that the distal surface is forced into the conical section. As the foldable member is forced further down the conical member and tubular member, the foldable member may assume a pleated configuration. Additional foldable members may then be inserted into the elongate tubular member.

In some variations, the profile member **3204** includes inner grooves or ridges to guide the foldable members into the delivery tube and control the folding. The grooves or ridges may be configured to interact with surface features on the foldable members, such as the surface features described above that are configured for relatively restraining two adjacent foldable members.

FIGS. **33**A and **33**B depict a side view and perspective view, respectively, of a rod **3300** configured to grasp a foldable member and insert the foldable member into a delivery device. Rod **3300** may generally comprise a handle **3302**, a transition section **3304**, and a distal head **3306**. Distal head **3306** may comprise two elongate parallel slits **3310** configured to receive a foldable member. Each slit may have a distal opening **3308** and a curved proximal end **3312**. The rod **3300** may be configured to reduce the profile of the foldable member by rotating the handle **3302** as the head **3306** pushes the foldable member into a profile reduction member. FIG. **33**B illustrates the head with a hollow central tube. The hollow central tube may allow for additional folding in the central region of the foldable member. In some variations, the diameter of the central tube **3314** is characterized as a percentage of the diameter **3316** of distal head **3306** and may sometimes be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages. Curved proximal end **3312** may be configured to cradle a perimeter portion of a foldable member. In some variations, the lengths of the elongate slits are characterized as percentages of the length of the head **3306** and sometimes may be 5%, 10%, 20%, 30%, 40%, 45%, 50%, 60%, 70%, 80%, 90%, or 95%, or any percentage range between any two of the above percentages.

FIGS. **34**A and **34**B illustrate top views of a foldable member **3404** before **3400** and after **3410** it is folded for insertion. FIG. **34**A illustrates the foldable member **3404** when it is inserted into the slots in the head **3402** of an insertion rod. FIG. **34**B illustrates the foldable member **3404** after it has been pushed in a profile reduction member of a delivery device (not shown). The foldable member **3404** in the after configuration **3400** generally take a reverse "S" shape. In other variations, the foldable member takes a different shape, such as a spiral or a wave, for example.

FIGS. **35**A and **35**B illustrate a proximal perspective view and a distal perspective view, respectively, of push device **3500**. Push device **3500** may be configured to force one or more foldable members through a delivery tube. Push device **3500** may comprise a suture channel **3508** configured to permit a suture connected to a foldable member to be run axially to the push device while the foldable member is being inserted. Push device **3500** may comprise a handle **3502** and a distal head **3504**. The diameter of distal head **3504** may be larger than the diameter of the handle **3502** to allow the suture to lie alongside the delivery tube. The diameter of the head **3504** may approximate the inside diameter of a desired delivery tube. FIG. **35**B illustrates a distal perspective view of push device **3500**, depicting a planar distal surface for pushing the foldable member through the delivery tube.

FIGS. **36**A and **36**B illustrate a side view and a distal perspective view, respectively, of push device **3600**. Push device **3600** comprises a handle **3602** and a head **3604**, similar to push device **3500**. Push device **3600** may also comprise a suture channel **3606** configured to permit a suture connected to a foldable member to run axially to the push device during delivery. Suture channel **3506** may be oriented at an angle to the main axis of push device **3600**, wherein the angle may be 0°, 10°, 20°, 30°, 40°, 50°, 60°, 70°, 80°, and 90°. Suture channel **3606** may also comprise a suture engagement structure **3610**. The angle of suture channel **3606** and the suture engagement structure **3610** may allow push device to engage and lock the suture within the head **3604** as the push device moves through the delivery tube. Engagement and locking of the suture may be achieved by twisting the push device **3600**.

Fistula tracts may be nonlinear or curvilinear and may contain cavities of varying sizes at different intervals within the tract. Fistulas may also comprise multiple interconnected or branching passages. A fistula treatment device disclosed herein may employ advantageous design, configuration techniques and attributes to accommodate such constraints and may be used, for example, in the treatment of anorectal fistulas. Some embodiments of fistula treatment devices may comprise irrigation and/or brushing devices which may be used, for example, to clean a fistula tract prior to, during, and/or after a procedure, and/or which may be used to clean a fistula tract prior to insertion of one or more implantable devices or other members (e.g., collagen plugs) therein.

Referring to FIG. **37**A, a fistula irrigation device (as shown, a fistula irrigation catheter **3710**) comprises a proximal end **3712** and a distal end **3714**. The fistula irrigation catheter further comprises a tubular member **3716** including a wall portion **3718** having a plurality of apertures **3720** therethrough. The tubular member has a proximal end **3713** and a distal end **3715**. In some embodiments, the length of the tubular member (between the proximal end **3713** and the distal end **3715**) may be in the range of about 20 centimeters to about 200 centimeters, such as about 40 centimeters to about 120 centimeters, about 40 centimeters to about 100 centimeters, or about 60 centimeters to about 90 centimeters.

The apertures **3720** may be used to irrigate a fistula tract—in other words, one or more irrigation fluids may flow through, or be sprayed or otherwise dispersed via, the apertures **3720**. In some embodiments, the distalmost aperture **20'** may be located at least about 2 centimeters (e.g., at least about 3 centimeters, at least about 4 centimeters, at least about 5 centimeters, at least about 10 centimeters, at least about 20 centimeters, at least about 30 centimeters, at least about 40 centimeters, at least about 50 centimeters, at least about 100 centimeters) from the distal end **3714** of the fistula irrigation catheter **3710**. In other words, a fistula irrigation catheter may include apertures that are offset from the distal end of the catheter. This may be advantageous because it may, for example, provide for irrigation of a greater region of a fistula tract (e.g., both proximal and distal irrigation) than an irrigation catheter that only has an irrigation aperture at its distal end.

FIG. **37**B provides a cross-sectional view of an aperture **3720** in a region of the wall portion **3718**. As shown there, the aperture **3720** has an axis **3722** therethrough that defines an angle **3723** relative to the exterior surface **3719** of the wall portion **3718**. In FIG. **37**B, the angle **3723** is shown as orthogonal (i.e., 90°)—however, in other embodiments, such an aperture angle may not be orthogonal. For example, the angle **3723** between an axis **3722** of an aperture **3720** and the exterior surface **3719** may be at least about 45° (e.g., at least about 60°, at least about 75°, at least about 90°, or from about 45° to about 180°, such as about 75°) relative to the distal end **14** of the catheter **3710**, and/or may be at most about 180° (e.g., at most about 135°, at most about 120°, at most about 105°, or from about 45° to about 180°, such as about 75° to about 135°, or about 105°) relative to the proximal end **3712** of the catheter **3710**.

While the apertures **3720** are depicted as generally oval or elliptical in shape, apertures in a fistula irrigation catheter may have any suitable shape, and may all be of the same shape or may have different shapes from each other. In some

embodiments, an aperture may be circular, triangular, or square. Other appropriate shapes may also be used. Moreover, the apertures may all have the same size or may have different sizes (e.g., to provide differing amounts of irrigation to different regions of a fistula tract).

In some embodiments, apertures may be radially positioned around a fistula irrigation device. For example, FIG. **37**C shows a fistula irrigation catheter **3740** having a proximal end **3742** and a distal end **3744**, and comprising a tubular member **3746** having a wall portion **3748** having a plurality of radially disposed apertures **3750** therethrough, including distalmost apertures **3750'**. As shown there, the apertures are arranged in two radial configurations. However, other embodiments of fistula irrigation catheters may have different arrangements and numbers of apertures. As an example, FIG. **37**D shows a fistula irrigation catheter **3760** having a proximal end **3762** and a distal end **3764**, and including a tubular member **3766** having a wall portion **3768**. The tubular member **3766** has a plurality of apertures **3770** therethrough, including distalmost apertures **3770'**. Of course, other configurations are possible, and any suitable number, size, shape and arrangement of apertures may be used in a fistula irrigation device.

In certain embodiments, apertures may be radially positioned around an irrigation catheter, and may be the distal termination points of radially oriented tubular members or lumens within the irrigation catheter. In some embodiments, a fistula irrigation device may comprise one or more infusion lumens that terminate at the location of one or more apertures in the device, such that the lumens do not extend any further distally, thereby avoiding creating "dead space" within the device. In certain embodiments, a fistula irrigation device may include one or more infusion lumens that extend distally beyond one or more apertures in the device; however, in some such embodiments, the infusion lumens may be plugged or otherwise filled distally of the apertures. In such cases, a guidewire lumen may be maintained open.

The tubular member **3716** of the fistula irrigation catheter **3710** may be relatively flexible in some embodiments and in certain embodiments, may include one or more relatively rigid regions. This may, for example, allow the tubular member **3716** to conform well to a tissue tract during use.

In certain embodiments, a fistula irrigation catheter may also have fistula brushing or debriding capabilities. As an example, FIG. **38**A depicts a fistula irrigation and brushing catheter **3800**. The catheter **3800** includes features similar to those described above with respect to the fistula irrigation catheter **3710**, such as irrigation apertures **3802**. However, the catheter **3800** also includes a brushing member **204** having bristles **3806**. When the catheter **3800** is used to irrigate a fistula tract, it may also be used to brush or debride the fistula tract, thereby further cleaning the tract. In some cases, the bristles **3806** may be formed of one or more polymers. Other appropriate materials may also be used. In certain embodiments, a sheath or other protective member (not shown) may be removably positioned over a brushing member to, for example, temporarily prevent the brushing member from brushing tissue (e.g., non-target tissue).

Of course, brushing members having different configurations may be used. For example, FIG. **38**B shows a portion of a fistula brushing catheter **3820** having bristles **3822** arranged similar to the bristles of a toothbrush, and FIG. **38**C shows a portion of a fistula brushing catheter **3830** having bristles **3832** arranged in a spiral pattern. Additionally, FIG. **38**D shows a fistula brushing catheter **3840** having two sets of radially disposed bristles **3842**. Of course, these are only exemplary embodiments, and other bristle arrangements may be used in fistula brushing devices. Moreover, some embodiments of fistula brushing devices may include bristles in different regions from those depicted herein.

It should be understood that while combination fistula irrigation and brushing or debriding devices have been described, in some cases a fistula treatment device may be configured to brush or debride a fistula tract without also irrigating the tract. Additionally, in some embodiments a fistula brushing device may not be in the form of a catheter. As an example, FIG. **39** shows a fistula brushing device **3900** comprising a proximal handle portion **3902**, a shaft **3904** extending from the handle portion **3902**, and a brushing member **3906** comprising bristles **3908**, where the brushing member **3906** is located in a distal portion **3910** of the shaft **3904**. Of course, while not shown here, certain embodiments of fistula brushing devices may include multiple brushing members, or may include one or more brushing members that are not located in a distal portion of the device or a component thereof. As shown, the fistula brushing device **3900** also comprises an elongated member **3912**, such as a suture or a string which may be used, for example, to help route the device **3900** into a fistula tract. For example, the elongated member **3912** may be attached to a guidewire that has been routed into a fistula tract, and the guidewire may be pulled upon to advance the fistula brushing device **3900** into the fistula tract. In some embodiments, however, a fistula treatment device may not include such an elongated member, or alternatively may include multiple such elongated members.

Any appropriate methods may be used to deliver or deploy the fistula treatment devices described herein. For example, FIGS. **40**A-**40**C depict an embodiment of a method of delivering the fistula irrigation catheter **3710** of FIG. **37***a* into an anorectal fistula tract **4000**. First, FIG. **40**A shows the fistula tract **4000**, by the anus **4002** and the dentate line **4004**. In FIG. **40**B, a guidewire **4006** has been passed through the fistula tract **4000**. Next, and referring to FIG. **40**C, the fistula irrigation catheter **3710** has been delivered into the fistula tract **4000**, over the guidewire **4006**. The guidewire **4006** may be maintained within the catheter **3710** in the fistula tract **4000**, or may be removed at this point.

Once the tubular member **3716** with the apertures **3720** is located within the fistula tract, the fistula irrigation catheter **3710** may be grasped at both its proximal and distal ends **3712** and **3714**, and moved back and forth within the tract **4000** (e.g., as illustrated by arrow **4008**), to effectively "floss" the tract **4000** and thereby irrigate different regions of the tract **4000**. This may, for example, provide for good cleaning and minimal contamination of the fistula tract **4000** (e.g., by providing for both proximal and distal irrigation of the fistula tract). Moreover, and as discussed above, the apertures **3720** may be oriented to spray irrigation fluid (e.g., saline) in a non-orthogonal direction—for example, some of the apertures **3720** may be forward-angled and some of the apertures **3720** may be backward-angled, so that bidirectional irrigation may be provided. Additionally, it should be noted that, while not shown here, fistula brushing members or devices may also be moved back and forth within a fistula tract in the manner described above.

To perform the procedures described above, a kit may be provided that contains, for example, one or more fistula irrigation devices, one or more fistula brushing devices, and/or one or more combination fistula irrigation and brushing devices. The kit may also contain one or more other items, including but not limited to a guidewire (e.g., a 0.038" guidewire), a peel-away sheath (e.g., a 7F, 8F, 9F, 10F, or 12F sheath), one or more syringes (e.g., 0.5 cc, 1 cc, 5 cc, and/or 10 cc syringes), saline or biocompatible fluid, contrast media,

a scalpel, one or more free needles, and non-resorbable sutures (e.g. 3-0 or 4-0 nylon suture). A fistula tract dilator may also be provided in the kit. The contents of a kit may be provided in sterile packages. Instructions may be provided on or with the kit, or alternatively via the Internet or another indirect method, and may provide direction on how to employ the kit (e.g., outlining a deployment method such as one of those described herein). While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that those examples are brought by way of example only. Numerous changes, variations, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that the methods and structures within the scope of these claims will be covered thereby.

What is claimed is:

**1**. A distal anchor for an implantable fistula treatment device, the distal anchor comprising:

a suture; and

a plurality of foldable members, including at least a distal-most foldable member and a proximal-most foldable member;

wherein the distal-most foldable member comprises a suture attachment structure;

wherein the proximal-most foldable member is configured to couple to a surface of a body lumen at a distal opening of a fistula, wherein the proximal-most foldable member is configured to occlude the fistula at the distal opening, and wherein the proximal-most foldable member is configured to slide along the suture attached to the suture attachment structure;

wherein the proximal-most foldable member comprises:

a proximal first average dimension substantially parallel to a longitudinal axis of the suture,

a proximal second average dimension orthogonal to the proximal first average dimension, and

a proximal third average dimension orthogonal to the proximal first and second average dimensions, the proximal first average dimension being no greater than 10% of the greater of the proximal second and third average dimensions;

wherein the distal-most foldable member comprises:

a distal first average dimension substantially parallel to the longitudinal axis of the suture,

a distal second average dimension orthogonal to the distal first average dimension, and

a distal third average dimension orthogonal to the distal first and second average dimensions, the distal first average dimension being no greater than 30% of the greater of the distal second and third average dimensions;

wherein at least one of the plurality of foldable members comprises a protrusion on a first surface; and

wherein at least another of the plurality of foldable members comprises a recess on a second surface that opposes the first surface, wherein the protrusion and the recess comprise complementary coupling members, such that the recess is configured to receive the protrusion to restrain relative movement of at least two of the plurality of foldable members.

**2**. The distal anchor of claim **1**, wherein the plurality of foldable members further comprises at least one additional foldable member positioned between the distal-most foldable member and the proximal-most foldable member.

**3**. The distal anchor of claim **1**, wherein the proximal second average dimension of the proximal-most foldable member is larger than the distal second average dimension of the distal-most foldable member.

**4**. The distal anchor of claim **3**, wherein the distal second average dimension of the distal-most foldable member is less than or equal to 20% of the proximal second average dimension of the proximal-most foldable member.

**5**. The distal anchor of claim **1**, wherein the proximal-most foldable member comprises a generally circular perimeter.

**6**. The distal anchor of claim **5**, wherein the proximal-most foldable member comprises a generally concave shape.

**7**. The distal anchor of claim **6**, wherein the distal-most foldable member comprises a generally concave shape, and wherein a radius of curvature of the distal-most foldable member is smaller than a radius of curvature of the proximal-most member.

**8**. The distal anchor of claim **1**, wherein the protrusion on the at least one foldable member comprises at least one tooth.

**9**. The distal anchor of claim **1**, further comprising an additional coupling member disposed between two of the plurality of foldable members, wherein the additional coupling member comprises a curing agent.

**10**. The distal anchor of claim **9**, wherein the additional coupling member further comprises a capsule enclosing the curing agent.

**11**. The distal anchor of claim **10**, where wherein the capsule is configured to rupture upon contact with another foldable member.

**12**. The distal anchor of claim **1**, wherein the coupling members are configured to produce attracting electromagnetic forces.

**13**. The distal anchor of claim **1**, wherein a flexibility of each of the foldable members decreases from the proximal-most to the distal-most foldable member.

**14**. The distal anchor of claim **13**, wherein the proximal first average dimension of the proximal-most foldable member is less than the distal first average dimension of the distal-most foldable member.

**15**. The distal anchor of claim **13**, wherein a density of the proximal-most foldable member is less than a density of the distal-most foldable member.

**16**. The distal anchor of claim **1**, wherein a proximal surface of the proximal-most foldable member comprises a grapple configured to attach the proximal-most foldable member to a surface of the body lumen.

**17**. The distal anchor of claim **16**, wherein a distal surface of the proximal-most foldable member comprises a grapple activation structure configured to activate the grapple upon contact with the proximal surface of another foldable member.

**18**. The distal anchor of claim **17**, wherein the grapple activation structure comprises a protrusion.

**19**. The distal anchor of claim **1**, wherein the protrusion comprises at least two protrusions, and wherein the recess comprises at least two recesses.

**20**. The distal anchor of claim **1**, wherein the distal-most foldable member is pre-attached to the suture at the suture attachment mechanism.

**21**. The distal anchor of claim **20**, wherein the proximal-most foldable member is not pre-attached to the suture.

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